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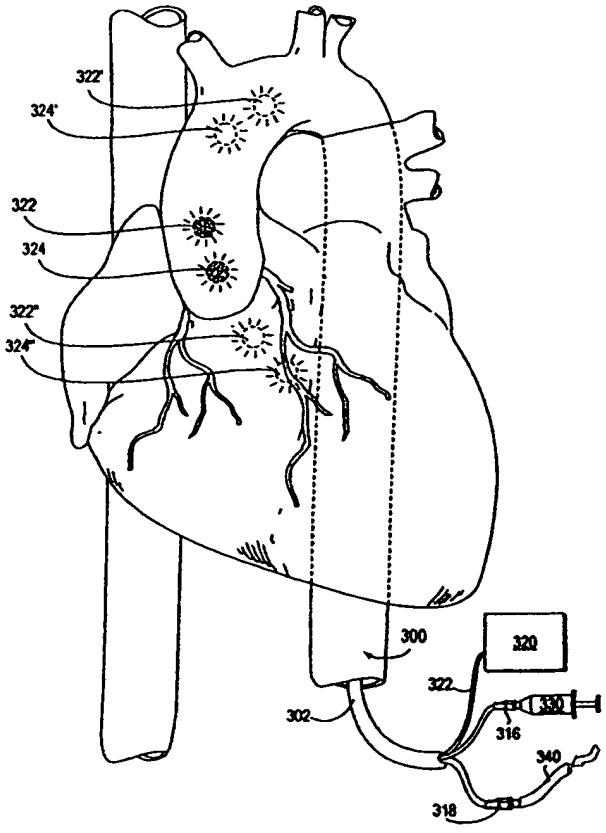
(54) Title: CARDIOVASCULAR CATHETER APPARATUS AND CATHETER POSITIONING METHOD USING TISSUE TRANSILLUMINATION

(57) Abstract

Arterial and venous cannulas or catheters are described incorporating means for tissue transillumination for positioning and for monitoring of the device within a blood vessel throughout a surgical procedure without expensive imaging equipment or ionizing radiation and without inconveniencing or complicating the procedure. Detailed descriptions of particular embodiments include: a single balloon catheter or cannula configured with optical fibers for tissue transillumination, a single balloon catheter or cannula configured with light emitting diodes or laser diodes for tissue transillumination, a single balloon catheter or cannula configured with battery powered light emitting diodes or laser diodes for tissue transillumination, a catheter or cannula with two selectively expandable external catheter valves configured for tissue transillumination, a single–balloon aortic catheter deployed within a patient's aorta via peripheral arterial access, a double–balloon aortic catheter for selective aortic perfusion of a patient's circulatory system, a two–valve aortic catheter for selective aortic perfusion, a two–lumen, double–balloon venous drainage cannula for isolated venous drainage of a patient's inferior and superior vena cava and a single–lumen, two–stage venous drainage cannula for simultaneous drainage of a patient's inferior and superior vena cava. Additional illumination means are described that can be used with any of the embodiments of catheters and cannulas. Included among these is a separate transillumination device in the form of a stylet or guidewire that is insertable into or through a lumen of the catheter or cannula.



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# CARDIOVASCULAR CATHETER APPARATUS AND CATHETER POSITIONING METHOD USING TISSUE TRANSILLUMINATION

## FIELD OF THE INVENTION

The present invention relates generally to cardiovascular catheters, particularly to aortic and venous catheters or cannulas for performing cardiopulmonary bypass, for inducing cardioplegic arrest and for segmenting and selectively perfusing a patient's circulatory system during cardiopulmonary bypass. More particularly, the present invention relates to cardiovascular catheters and catheter positioning methods using tissue transillumination for localization and monitoring of the catheter position.

## BACKGROUND OF THE INVENTION

Cardiopulmonary bypass is an important enabling technology that has allowed the development and refinement of many complex and life saving cardiothoracic surgical techniques. Cardiopulmonary bypass (CPB) systems are used to temporarily replace the functions of the heart and the lungs by supplying a flow of oxygenated blood to the patient's circulatory system. The CPB system drains deoxygenated from the patient's venous system, passes it through a blood oxygenator, and pumps the oxygenated blood back into the patient's arterial system. CPB systems may be configured for direct cannulation of the inferior and superior vena cava and/or the right atrium and of the aorta, or they may be configured for peripheral cannulation through the femoral vein or jugular vein and the femoral artery. The cardiopulmonary bypass system allows the patient's heart to be temporarily stopped, for example by cardioplegic arrest, hypothermic arrest or fibrillation, for performing a variety of cardiothoracic surgical procedures. In standard open-chest cardiac surgery, before inducing cardioplegic arrest, a cross clamp is applied to a patient's ascending aorta to occlude the aorta and isolate the heart from the remainder of the circulatory system. Because the patient's chest is open, the aortic cross clamp, the arterial cannula and the venous cannula for CPB can be placed by the surgeon under direct vision and with direct tactile feedback without the need for radiographic or endoscopic imaging.

However, recent advances in the field of cardiac surgery have included new techniques in minimally invasive or closed-chest surgical techniques that have limited access to and decreased visibility of the surgical field. In minimally invasive or closed-chest cardiac surgery, radiographic imaging, ultrasonic imaging and endoscopic visualization have become more important, particularly for placement of the arterial and venous cannulas or catheters. It would be desirable to provide arterial and venous cannulas or catheters for cardiopulmonary bypass that reduce the reliance on direct visualization and tactile feedback or radiographic and ultrasonic imaging for placement of the cannulas using open-chest or minimally invasive surgical approaches.

Recent advances in the field of minimally invasive cardiac surgery have included the development of aortic catheters and methods for inducing cardioplegic arrest without the necessity of opening the patient's chest with a sternotomy or other major thoracotomy. For example, U.S. patent Re 35,352 to Peters describes a single-balloon catheter for occluding a patient's ascending aorta and a method for inducing cardioplegic arrest. A perfusion lumen or a contralateral arterial cannula is provided for supplying oxygenated blood during cardiopulmonary bypass. U.S. patent 5,584,803 to Stevens et al. describes a single-balloon catheter for inducing cardioplegic arrest and a system for providing cardiopulmonary support during closed-chest cardiac surgery. A coaxial arterial cannula is provided for supplying oxygenated blood during cardiopulmonary bypass. The occlusion balloon of these catheters must be very carefully placed in the ascending aorta between the coronary arteries and the brachiocephalic artery, therefore the position of the catheter must be continuously monitored to avoid complications. In clinical use, these single-balloon catheters have shown a tendency to migrate in the direction of the pressure gradient within the aorta. That is to say , when the CPB pump is on, the balloon catheter will tend to migrate upstream into the aortic root, sometimes even crossing the aortic valve, due to the higher pressure on the downstream side of the balloon. During infusion of cardioplegia, the balloon catheter will tend to migrate downstream due to the higher pressure on the upstream side of the balloon. This migration can be problematic if the balloon migrates far enough to occlude the brachiocephalic artery on the downstream side or the coronary arteries on the upstream side. PCT patent application WO 9721462 by Fan et al. attempts to overcome this problem with a balloon catheter having

high friction areas on the outer surface of the balloon. A problem with this single-balloon approach is that a relatively large balloon is needed to create enough friction to avoid migration of the inflated balloon. The larger the balloon is, the more carefully it must be placed in the ascending aorta to avoid occluding the coronary arteries or the brachiocephalic artery and the less margin of error there is should any balloon migration occur. U.S. patent to 5,312,344 to Grinfeld et al. describes an arterial perfusion cannula having two closely spaced balloons positioned in the ascending aorta. However, this patent does not provide any guidance on how to avoid migration or inadvertent occlusion of the coronary arteries or the brachiocephalic artery. It would be desirable to provide an aortic occlusion catheter for inducing cardioplegic arrest that minimizes the likelihood of migration of the balloon or occluding member in the ascending aorta.

The critical importance of proper balloon placement in these prior art devices requires that the catheters be positioned using fluoroscopic guidance. Furthermore, the tendency for the occlusion balloon to migrate requires that the balloon position be monitored continuously throughout the procedure using fluoroscopy and/or transesophageal echocardiography (TEE). This requirement presents a number of significant drawbacks. The surgical suite must be equipped with expensive fluoroscopic and/or ultrasonic imaging equipment and there must be additional staff to operate the equipment, both of which add significantly to procedure costs. Another problem is that the fluoroscopic imaging equipment crowds the surgical field, preventing access to the patient's chest while imaging. Consequently, the C-arm of the fluoroscopy unit must be moved in and out of the surgical field to allow access to the patient's chest for surgery. This is inconvenient, it interrupts the surgical procedure and it presents a danger of contaminating the surgical field. Fluoroscopy exposes the patient, the surgeon and all of the operating room personnel to significant levels of X-ray radiation. The surgeon and all of the operating room personnel must wear protective lead aprons throughout the procedure to protect themselves against scattered radiation. The lead aprons are heavy and uncomfortable, which causes fatigue and presents a danger of back injury, and they interfere with the surgeon's mobility and dexterity while performing surgery. Fluoroscopy also involves injection of radiopaque contrast agents, which are mildly toxic, particularly to the patient's kidneys, and which cause serious allergic reactions in some patients. Since the

fluoroscopic imaging is only intermittent, there is still a danger of the catheter migrating while it is unobserved. Transesophageal echocardiography is capable of continuously monitoring the catheter position within the patient's ascending aorta, so it is useful as an adjunct to fluoroscopic imaging. However, TEE alone is not sufficient for monitoring catheter position because its narrow field of view does not allow imaging of the catheter as it is inserted at its peripheral entry site or as it is advanced up the descending aorta. Additionally, although TEE does not involve ionizing radiation, it is an invasive imaging technique that presents inherent difficulties and dangers, as well as causing some patient discomfort. It would be desirable to provide an aortic catheter apparatus and a method for positioning the catheter that reduces or eliminates the need for fluoroscopic and ultrasonic imaging. The catheter apparatus and the method should allow precise localization of the catheter during positioning within the patient's aorta and should allow continuous monitoring of the catheter position throughout the surgical procedure. Preferably, these objectives should be accomplished without the use of ionizing radiation and without the need for cumbersome protective equipment. This should also be accomplished without crowding the surgical field and without interfering with the surgical procedure being performed.

Another important development in the areas of cardiopulmonary support and of aortic balloon catheters is the concept of selective aortic perfusion. US 5308320, 5383854, 5820593 and 5906588 by Peter Safar, S. William Stezoski, and Miroslav Klain describe a balloon catheter for segmenting a patient's aorta for selective perfusion of different organ systems within the body. Other US patents which address the concept of selective aortic perfusion include commonly owned, copending patent applications, 08/909,293 filed 8/11/97 and 09/152,589 filed 9/11/98, by Safar et al.; US 5738649 by John A. Macoviak and commonly owned copending patent application 09/060,412, filed 4/14/98 by John A. Macoviak; and US 5827237 and 5833671 08/665,635, filed 6/17/96, by John A. Macoviak and Michael Ross; and commonly copending patent application09/205,753, filed 12/4/98, by Bresnahan et al. In addition, commonly owned, copending patent application 60/084,835, filed 6/9/98 by Macoviak et al. describes a circulatory support system and method of use for isolated segmental perfusion. These patent applications and all other patents referred to herein are hereby incorporated by reference in their entirety. Selective perfusion can be used to

prioritize the flow of oxygenated blood or other protective fluids to the various organ systems, with different temperatures or compositions, for achieving optimal preservation of all organ systems within the body. With these catheters for selective aortic perfusion, as with the prior art single-balloon catheters, proper placement of the catheters is important for effective segmentation of the aorta and for avoiding complications due to the inadvertent occlusion of the brachiocephalic artery or the coronary arteries. It is desirable therefore to provide selective aortic perfusion catheters and methods for positioning the catheters that reduce or eliminate the need for fluoroscopic and ultrasonic imaging. These apparatus and methods should also allow precise localization of the catheter during positioning within the patient's aorta and should allow continuous monitoring of the catheter position throughout the surgical procedure without ionizing radiation and without inconveniencing or complicating the procedure.

Tissue transillumination offers one possible solution for precise localization of arterial and venous cannulas or catheters during positioning within a patient's blood vessels and for continuous monitoring of the device position throughout a surgical procedure without ionizing radiation and without inconveniencing or complicating the procedure. Tissue transillumination has been suggested for guiding needles, catheters or other devices for cannulation of soft tissues of the body. See, for example, US 4566438; 5131380; 5237985 and 5517997. Tissue transillumination has also been suggested for diagnosis of tumors in soft tissues of the body; see US patent 4898172. Tissue transillumination has also been suggested for guidance of endotracheal tubes during intubation; see US patents 4567882 and 5163941. In addition, tissue transillumination has been suggested for guidance of a retrograde cardioplegia catheter into the coronary sinus during standard open-chest cardiac surgery; see US patent 5370640. Heretofore, however, there has been no suggestion of using tissue transillumination for localization and monitoring of arterial perfusion cannulas or catheters and venous drainage cannulas or catheters for performing cardiopulmonary bypass. The known prior art devices and methods are unsuitable for application in arterial or venous cannulation for cardiopulmonary bypass and particularly unsuitable for application in closed-chest cardiac surgery using percutaneous, thoracoscopic, port and/or mini-thoracotomy techniques. One important reason why tissue transillumination has not previously been

considered for arterial or venous cannulation for cardiopulmonary bypass is that the light from a transillumination device cannot readily penetrate through the dense, bony structure of the rib cage the way that it can through soft tissue. However, when coupled with the newly emergent imaging techniques used for minimally invasive or closed-chest cardiac surgery, tissue transillumination of the great vessels of the circulatory system becomes a powerful technique for positioning and monitoring cardiopulmonary bypass cannulas. The relative opacity of the rib cage becomes an advantage because the light from the transillumination device is brightly visible through the blood vessel walls within the darker environment of the chest cavity. Tissue transillumination is also a useful technique for positioning and monitoring cardiopulmonary bypass cannulas in open-chest cardiac surgery, particularly when coupled with certain techniques for increasing the visibility of the light from the transillumination device without having to dim the lights of the operating room.

## SUMMARY OF THE INVENTION

Accordingly, the present invention provides arterial and venous cannulas or catheters incorporating one or more illumination means for performing tissue transillumination to facilitate precise localization of the device during positioning within a patient's blood vessel and for continuous monitoring of the device position throughout a surgical procedure without expensive imaging equipment or ionizing radiation and without inconveniencing or complicating the procedure.

General descriptions of various preferred embodiments of catheters or cannulas with illumination means according to the apparatus of the present invention and a general description of their operation according to the method of blood vessel tissue transillumination of the invention are given. Included in these general descriptions are: a single balloon catheter or cannula configured with optical fibers for tissue transillumination, a single balloon catheter or cannula configured with light emitting diodes or laser diodes for tissue transillumination, a single balloon catheter or cannula configured with battery powered light emitting diodes or laser diodes for tissue transillumination and a catheter or cannula with two selectively expandable external catheter valves configured for tissue transillumination. Following are

detailed descriptions of particular embodiments of the apparatus of the present invention shown applying the method of blood vessel tissue transillumination in clinical use with modifications and additions specific to their clinical applications. Included in the detailed descriptions of particular embodiments are: a single-balloon aortic catheter deployed within a patient's aorta via peripheral arterial access, a double-balloon aortic catheter for selective aortic perfusion of a patient's circulatory system, a two-valve aortic catheter for selective aortic perfusion, a two-lumen, double-balloon venous drainage cannula for isolated venous drainage of a patient's inferior and superior vena cava and a single-lumen, two-stage venous drainage cannula for simultaneous drainage of a patient's inferior and superior vena cava. Additional illumination means are described for tissue transillumination of a blood vessel that can be used with any of the described embodiments of catheters and cannulas. Included among these is a separate transillumination device in the form of a stylet or guidewire that is insertable into or through a lumen of the catheter or cannula.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG 1 shows a side view of a single balloon catheter or cannula configured with optical fibers for tissue transillumination according to the present invention;

FIG 2 shows a cutaway side view of a single balloon catheter or cannula configured with light emitting diodes or laser diodes for tissue transillumination according to the present invention;

FIG 3 shows a side view of a single balloon catheter or cannula configured with battery powered light emitting diodes or laser diodes for tissue transillumination according to the present invention;

FIG 4 shows the catheter of FIG 1, 2 or 3 positioned within a patient's blood vessel with the inflatable balloon in the deflated state;

FIG 5 shows the catheter of FIG 1, 2 or 3 positioned within a patient's blood vessel with the inflatable balloon in the inflated state;

FIG 6 shows a side view of a catheter or cannula with two selectively expandable external catheter valves configured for tissue transillumination according to the present invention;

FIG 7 shows the catheter of FIG 6 positioned within a patient's blood vessel with the external catheter valve in the unexpanded state;

FIG 8 shows the catheter of FIG 6 positioned within a patient's blood vessel with the external catheter valve in the expanded state;

FIG 9 is a cutaway view of a patient's heart showing a single-balloon aortic catheter deployed within a patient's aorta via femoral artery access;

FIG 10 is an anterior view of a patient's heart with the catheter of FIG 9 deployed within the patient's aorta. The position of the catheter and the inflation state of the balloon can be determined by the location and intensity of the bright spots created by the illumination means of the catheter;

FIG 11 is a cutaway view of a patient's heart showing a double-balloon aortic catheter for selective perfusion deployed within a patient's aorta via femoral artery access;

FIG 12 is a cutaway view of a patient's heart showing a two-valve aortic catheter for selective perfusion deployed within a patient's aorta via femoral artery access;

FIG 13 is a cutaway view of a patient's heart showing a two-lumen, double-balloon venous drainage cannula deployed within a patient's inferior and superior vena cava;

FIG 14 is an anterior view of a patient's heart with the cannula of FIG 13 deployed within the patient's inferior and superior vena cava. The position of the cannula and, optionally, the inflation state of the balloons can be determined by the location and intensity of the bright spots created by the illumination means of the cannula;

FIG 15 is a cutaway view of a patient's heart showing a single-lumen, two-stage venous drainage cannula deployed within a patient's inferior and superior vena cava;

FIG 16 is a longitudinal cross section of a catheter or cannula showing an alternate illumination means for tissue transillumination of a blood vessel;

FIG 17 is a longitudinal cross section of a catheter or cannula showing another alternate illumination means for tissue transillumination of a blood vessel;

FIG 18 is a longitudinal cross section of a catheter or cannula showing another alternate illumination means for tissue transillumination of a blood vessel; and

FIG 19 is a longitudinal cross section of a catheter or cannula having a separate transillumination device in the form of a stylet or guidewire that is insertable into or through a lumen of the catheter shaft;

## DETAILED DESCRIPTION OF THE INVENTION

The detailed descriptions given below in connection with FIGS 1-5 and 6-8 are general descriptions of various preferred embodiments of catheters or cannulas according to the apparatus of the present invention and a general description of their operation according to the method of the invention. Following the general descriptions are detailed descriptions of particular embodiments of the present invention shown in clinical use with modifications and additions specific to their clinical applications.

FIG 1 shows a side view of a first embodiment of a catheter or cannula 100 according to the present invention. The catheter 100 has an elongated flexible tubular shaft 102 having a proximal end 106 and a distal end 108. The elongated tubular shaft 102 is preferably made of a flexible polymer or elastomer or a reinforced polymer composite. Suitable materials for the elongated tubular shaft 102 include, but are not limited to, polyvinylchloride, polyurethane, polyethylene, polypropylene, polyamides (nylons), polyesters, fluoropolymers, silicone, latex, and alloys or copolymers thereof, as well as braided, coiled or counterwound wire or filament reinforced composites. Generally, one or more expandable flow control members are mounted on the elongated tubular shaft 102. In this illustrative embodiment, an expandable flow control member in the form of an expandable inflatable balloon 104 is mounted on the elongated tubular shaft 102 near the distal end 108. The inflatable balloon has a deflated or unexpanded state 104 shown in solid lines, where the diameter of the unexpanded balloon 104 is not much larger than the diameter of the elongated tubular shaft 102, and an inflated or expanded state 104' shown in dashed lines, where the diameter of the balloon 104' expands to control or to occlude fluid flow through the blood vessel in which the catheter 100 is inserted. For use in the great vessels of the circulatory system, such as in the aorta or the vena cava, the balloon 104' preferably has an expanded diameter from approximately 10 to 70 mm, more preferably from approximately 25 to 40 mm. For pediatric patients the sizes may be smaller. Suitable materials for the inflatable balloon 104 include flexible thermoset rubber, thermoplastic polymers and elastomers, which include, but are not limited to, polyvinylchloride, polyurethane, polyethylene, polypropylene, polyamides (nylons), polyesters, latex, silicone, and alloys, copolymers and reinforced composites thereof. The

catheter 100 may include additional balloons mounted at other positions along the elongated tubular shaft 102.

The elongated tubular shaft 102 includes a balloon inflation lumen 110 that extends from the proximal end 106 to a balloon inflation port 112 positioned within the inflatable balloon 104. If the catheter 100 includes additional balloons, the elongated tubular shaft 102 may include additional balloon inflation lumens for independent inflation of each balloon or the balloons may be connected to a common balloon inflation lumen 110 for simultaneous inflation. Preferably, the elongated tubular shaft 102 also includes a distal lumen 114 that extends from the proximal end 106 to a distal port 116 near the distal end 108 of the catheter 100. The distal lumen 114 may be used for insertion of a guidewire or stylet for guidance and manipulation of the catheter 100 and/or for perfusion or drainage of fluids through the distal port 116. The elongated tubular shaft 102 may include additional lumens for perfusion or drainage of fluids through additional ports that may be located proximal to the inflatable balloon 104 distal to and/or between balloons if additional balloons are present. The elongated tubular shaft 102 preferably has an external diameter from approximately 8 to 30 French (approximately 2.7 to 10 mm diameter) depending on the number of lumens and the desired perfusion or drainage flow rate through each of the lumens.

The catheter 100 includes at least one illumination means for emitting a beam of light from the catheter located near the distal end 108 of the elongated tubular shaft 102 and/or within the vicinity of the inflatable balloon 104. If the catheter 100 includes additional inflatable balloons, the catheter 100 may include one or more illumination means for each of the additional inflatable balloons. In this illustrative embodiment, the catheter 100 includes a first and second illumination means in the form of a first optical fiber 118 and a second optical fiber 122 that are coupled to an external light source (not shown). The first optical fiber 118 extends through the elongated tubular shaft 102 from the proximal end 106 to a first light emitting distal tip 120 located within the inflatable balloon 104. The second optical fiber 122 extends through the elongated tubular shaft 102 from the proximal end 106 to a second light emitting distal tip 124 located distal to the inflatable balloon 104 near the distal end 108 of the elongated tubular shaft 102. The first and second optical fibers 118, 122 may be

embedded in the wall of the elongated tubular shaft 102 or they may extend through a lumen in the elongated tubular shaft 102. In one preferred embodiment of the invention, the first and second optical fibers 118, 122 are a permanent, integrated part of the catheter 100. In alternate embodiments, one or more optical fibers or other illumination means may be provided as part of a separate transillumination device insertable into or through a lumen of the elongated tubular shaft 102, in the manner of a stylet, guidewire, or actuating rod. The first and second light emitting distal tips 120, 124 may emit a diffuse glow of light or they may be shaped to emit a focused or shaped beam of light or multiple beams of light. In one preferred embodiment, the first and second light emitting distal tips 120, 124 are formed by beveling the distal ends of the first and second optical fibers 118, 122 to create reflective surfaces, which may reflect by total internal reflection or by virtue of a reflective coating added to the beveled surfaces, that direct a first light beam 126 and second light beam 128 approximately perpendicular or at another chosen angle to the elongated tubular shaft 102. Shaped reflective surfaces, refractive lenses and/or apertures may be used to focus and/or shape the first and second light beams 126, 128. Alternatively, multiple reflective surfaces or a multifaceted prism may be used to create two, three or more beams of light from each illumination means.

FIG 2 shows a side view of an alternate construction of the catheter 100 of FIG 1 wherein a first and second illumination means are provided in the form of a first light emitting diode or laser diode 130 and a second light emitting diode or laser diode 134 that are coupled to an external power source by electrical leads 132, 136 that extend through the elongated tubular shaft 102.

FIG 3 shows a side view of another alternate construction of the catheter 100 of FIG 1 wherein a first and second illumination means are provided in the form of a first light emitting diode or laser diode 140 coupled to an internal power source such as a first miniature battery 142 and a second light emitting diode or laser diode 144 coupled to an internal power source such as a second miniature battery 146. Alternatively, the first and second light emitting diodes or laser diodes 140, 144 may be coupled to a single miniature battery mounted within the elongated tubular shaft 102. One or more switches or other activation

means may be provided for activating the first and second light emitting diodes or laser diodes 140, 144.

Alternatively, the illumination means may be provided in the form of one or more incandescent, fluorescent or chemoluminescent lights or other known light emitting technologies. Preferably, the catheter 100 includes on the proximal end 106 of the elongated tubular shaft 102 a connector (not shown) with fittings, such as Luer fittings or the like, for each of the lumens and with electrical or optical connectors, as appropriate, for each of the illumination means.

FIGS 4 and 5 show cutaway views of the catheter 100 of FIG 1, 2 or 3 *in vivo* positioned within a patient's blood vessel V. FIG 4 shows the catheter 100 positioned within the patient's blood vessel V, which may be the aorta or vena cava or other blood vessel, with the inflatable balloon 104 in the deflated state. The first light beam 126 and the second light beam 128 are directed through the wall of the blood vessel V and are visible as bright spots 126', 128' on the exterior of the blood vessel V. These bright spots 126', 128' are shown above the blood vessel V in the drawings for ease of illustration. The location of the bright spots 126', 128' can also give the operator additional information about the orientation of the catheter. The ability to detect the orientation of the catheter will be further enhanced if the first light beam 126 and the second light beam 128 have distinguishing characteristics, such as having different colors or different shapes for the light beams, or having one flashing and one steady light beam or two flashing light beams. The use of different colored or flashing light beams will also enhance the contrast and visibility of the transillumination device in a brightly lit environment, for instance when used in connection with open-chest cardiac surgery techniques.

Preferably, the first light beam 126 and the second light beam 128 are selected to have a frequency and intensity that are transmitted well through venous and/or arterial blood and through tissue without damage to either. However, some attenuation of the light beams 126, 128 is inevitable as they pass through the blood and through the wall of the blood vessel V, as indicated schematically by the dotted lines 126, 128 in FIG 4. This characteristic is used to

advantage in the present invention. FIG 5 shows the catheter 100 of FIG 4 within the blood vessel V with the inflatable balloon 104' expanded to occlude or control fluid flow through the blood vessel V. Preferably, the balloon 104' is inflated with a clear, nontoxic fluid, such as saline solution. The first light beam 126 is less attenuated by the clear fluid within the balloon 104' than by the blood, as indicated schematically by the solid lines 126 in FIG 5. Consequently, when the balloon 104 is inflated, the bright spot 126" from the first light beam 126 is brighter and more visible on the exterior of the blood vessel V. This gives a positive visual indication to the operator to confirm the expanded or inflated state of the inflatable balloon 104'.

FIG 6 shows a side view of a second embodiment of a catheter or cannula 200 according to the present invention. The catheter 200 has an elongated flexible tubular shaft 202 having a proximal end 208 and a distal end 210. The elongated tubular shaft 202 is preferably made of a flexible polymer or elastomer or a reinforced polymer composite material, similar to the catheter 100 of FIG 1. Generally, one or more expandable flow control members are mounted on the elongated tubular shaft 202. In this illustrative embodiment, a distal first expandable flow control member 204 and a proximal second expandable flow control member 206 are provided in the form of selectively expandable external catheter valves. Suitable constructions for the selectively expandable external catheter valves 204, 206 are described in US 5827237, 5833671and commonly owned, copending patent applications 08/665,635 which have previously been incorporated by reference. The first and second expandable flow control members have an unexpanded state 204, 206 shown in solid lines, in which the selectively expandable external catheter valves are collapsed around the elongated tubular shaft 202, and an expanded state 204', 206' shown in dashed lines, in which the selectively expandable external catheter valves expand to control or to occlude fluid flow through the blood vessel in which the catheter 200 is inserted. In one particularly preferred embodiment, the first expandable flow control member 204 is an antegrade external catheter valve that allows greater flow in the antegrade direction than the retrograde direction and the second expandable flow control member 206 is a retrograde flow external catheter valve that allows greater flow in the retrograde direction than the antegrade direction. For use in the great vessels of the circulatory system, such as in the aorta or the

vena cava, the first and second expandable flow control members 204', 206' preferably have an expanded diameter from approximately 10 to 70 mm, more preferably from approximately 25 to 40 mm.

The elongated tubular shaft 202 may include one or more actuation members 212 and/or actuation lumens for deploying the selectively expandable external catheter valves of the first and second expandable flow control members 204, 206. The elongated tubular shaft 202 also includes a distal lumen 214 that extends from the proximal end 208 to a distal port 216 near the distal end 210 of the catheter 200. The distal lumen 214 may be used for insertion of a guidewire or stylet for guidance and manipulation of the catheter 200 and/or for perfusion or drainage of fluids through the distal port 216. The elongated tubular shaft 202 also includes an intermediate lumen 218 that extends from the proximal end 208 to one or more intermediate ports 220 located on the elongated tubular shaft 202 between the first and second expandable flow control members 204, 206. The intermediate lumen 218 may be used for perfusion or drainage of fluids through the intermediate ports 220. The elongated tubular shaft 202 may include additional lumens, for example for perfusion or drainage of fluids through additional ports that may be located proximal to the first and second expandable flow control members 204, 206. The elongated tubular shaft 202 preferably has an external diameter from approximately 8 to 30 French (approximately 2.7 to 10 mm diameter) depending on the number of lumens and the desired perfusion or drainage flow rate through each of the lumens.

The catheter 200 includes at least one illumination means for emitting a beam of light from the catheter located near the distal end 210 of the elongated tubular shaft 202 and/or within the vicinity of the first and second expandable flow control members 204, 206. The illumination means may be provided in the form of optical fibers, light emitting diodes, laser diodes, incandescent, fluorescent or chemoluminescent lights or other known light emitting technologies. The illumination means may emit a diffuse glow of light or a focused or shaped beam of light. In this illustrative embodiment, the catheter 200 includes a first and second illumination means 222, 224 associated with the first expandable flow control member 204 and a third and fourth illumination means 226, 228 associated with the second expandable

flow control member 206. The first illumination means 222 is located on the elongated tubular shaft 202 distal to the first expandable flow control member 204 and the second illumination means 224 is located near the outer periphery of the selectively expandable external catheter valve. If desired, the second illumination means 224 may include multiple light emitting elements around the outer periphery of the selectively expandable external catheter valve of the first expandable flow control member 204, particularly if the selectively expandable external catheter valve includes multiple valve leaflets. The third illumination means 226 is located on the elongated tubular shaft 202 proximal to the second expandable flow control member 206 and the fourth illumination means 228 is located near the outer periphery of the selectively expandable external catheter valve. If desired, the fourth illumination means 228 may also include multiple light emitting elements around the outer periphery of the selectively expandable external catheter valve of the second expandable flow control member 206, particularly if the selectively expandable external catheter valve includes multiple valve leaflets.

Preferably, the catheter 200 includes on the proximal end 208 of the elongated tubular shaft 202 a connector (not shown) with fittings, such as Luer fittings or the like, for each of the lumens and with electrical or optical connectors, as appropriate, for each of the illumination means.

FIGS 7 and 8 are cutaway views showing a distal portion of the catheter 200 of FIG 6 with the first expandable flow control member 204 *in vivo* positioned within a patient's blood vessel V. FIG 7 shows the catheter 200 positioned within the patient's blood vessel V, which may be the aorta or vena cava or other blood vessel, with the first expandable flow control member 204 in the unexpanded state. A first light beam 230 from the first illumination means 222 and a second light beam 232 from the second illumination means 224 are directed through the wall of the blood vessel V and are visible as bright spots 230', 232' on the exterior of the blood vessel V. These bright spots 230', 232' are shown above the blood vessel V in the drawings for ease of illustration. The location of the bright spots 230', 232' on the exterior of the blood vessel V gives a clear indication of the location of the catheter 200 and whether it is in a safe position to expand the first expandable flow control member 204. The location of the

bright spots 230', 232' can also give the operator additional information about the orientation of the catheter, particularly if the first light beam 230 and the second light beam 232 have distinguishing characteristics, such as having different colors or different shapes for the light beams, or having one flashing and one steady light beam.

FIG 8 shows the catheter 200 of FIG 7 within the blood vessel V with the first expandable flow control member 204' expanded to control or occlude fluid flow through the blood vessel V. The second illumination means 224 located on the outer periphery of the first expandable flow control member 204 is brought into close contact with the wall of the blood vessel V. As previously described, the first light beam 230 and the second light beam 232 are selected to have a frequency and intensity that are transmitted well through venous and/or arterial blood and through tissue without damage to either, however, some attenuation of the light beams 230, 232 is inevitable as they pass through the blood. Consequently, when the first expandable flow control member 204 is expanded 204', the bright spot 232" from the first light beam 232 is brighter, less diffuse and more visible on the exterior of the blood vessel V. This gives a positive visual indication to the operator to confirm the expanded state of the first expandable flow control member 204'. The operative description of the first expandable flow control member 204 and the first and second illumination means 222, 224 given in connection with FIGS 7 and 8 applies equally well to the second expandable flow control member 206 and the third and fourth illumination means 226, 228, therefore further detailed description is deemed unnecessary.

FIG 9 is a cutaway view of a patient's heart showing a single-balloon aortic catheter 300, similar to the catheter 100 described in connection with FIGS 1-5, deployed within a patient's aorta. The catheter 300 has been configured for retrograde deployment in a patient's aorta via peripheral arterial access by percutaneous Seldinger technique or by an arterial cutdown of the femoral artery. Other modifications may be made to the catheter 300 for retrograde deployment via the subclavian or axillary artery or for antegrade deployment via direct central access into the ascending aorta. Such modifications are well described in commonly owned, copending patent application 60/067,945, which has previously been incorporated by reference. For femoral artery deployment in adult human patients, the

elongated flexible tubular shaft 302 of the catheter preferably has a length of approximately 60 to 120 cm, more preferably 70 to 90 cm, and an outer diameter of approximately 9 to 26 French (3.0-8.7 mm diameter), more preferably 12 to 22 French (4.0-7.3 mm diameter). The tubular shaft 302 is precurved with an approximately J-shaped curve 304 skewed slightly out of plane that approximates the curve of the aortic arch. A single aortic occlusion balloon 306 with an expanded diameter of approximately 25 to 40 mm is mounted near the distal end of the tubular shaft 302. A first illumination means 308 is located within the balloon 306 and a second illumination means 310 is located on the tubular shaft 302 distal to the balloon 306. The first and second illumination means 308, 310 are preferably positioned to emit a first and second beam of light approximately perpendicular to the plane of the J-shaped curve 304 so that the light beams will be visible on the anterior aspect of the ascending aorta when the catheter 300 is deployed. Alternatively, first and second illumination means 308, 310 may be configured to emit multiple light beams so that at least one will be visible as a bright spot on the ascending aorta no matter what the orientation of the catheter 300 is.

An inflation fitting 316, such as a Luer fitting, stopcock or the like, is provided at the proximal end of the catheter 300 for connection to a syringe or other balloon inflation device 330 for inflating the balloon 306 through a balloon inflation port 314 on the catheter shaft 302. A perfusion fitting 318, which may be a Luer fitting, barb connector or a standard tapered perfusion fitting, is provided for connection to a perfusion pump 340 or the like for perfusing a cardioplegic agent or other fluids through a distal port 312 on the catheter shaft 302 or for aspirating fluid from the aortic root. If required, a connector 322 is provided at the proximal end of the catheter 300 for connection to a light source 320, such as a xenon lamp, halogen lamp or a laser, or to an electrical power source, as appropriate.

For establishing cardiopulmonary bypass, the catheter 300 may be used with a contralateral, collateral or coaxial arterial perfusion cannula. Alternatively, the catheter shaft 302 may be provided with an additional perfusion lumen with perfusion ports located proximal to the balloon 306 for providing corporeal perfusion.

FIG 10 is an anterior view of the patient's heart with the catheter 300 of FIG 9 deployed within the patient's aorta. The patient's heart has been exposed via median sternotomy, a lateral thoracotomy, a mini-thoracotomy or by port-access or thoracoscopic techniques. The catheter 300 is not visible, except for the two bright spots 322, 324 on the anterior surface of the aorta created by the first and second illumination means 308, 310. The position of the catheter 300 and the inflation state of the balloon 306 can be determined by the location and intensity of the two bright spots 322, 324 without the need for fluoroscopic or ultrasonic imaging techniques. Positions 322' and 324' are high on the ascending aorta or within the aortic arch indicating that the catheter 300 is positioned too far downstream. Inflation of the balloon 306 in this position carries a danger of occluding the brachiocephalic artery or other arch vessels and possibly causing ischemia in the patient's brain if there is not sufficient collateral circulation. Positions 322" and 324" are low on the ascending aorta in the aortic root or even possibly beyond the aortic valve indicating that the catheter 300 is positioned too far upstream. Inflation of the balloon 306 in this position carries a danger of occluding the coronary arteries, which would interfere with establishing cardioplegic arrest and could cause ischemia in the patient's myocardium, or of distending the patient's ventricle if the balloon 306 or the distal port 312 are beyond the aortic valve. Positions 322 and 324 show that the catheter 300 is properly positioned with the balloon 306 located between the coronary arteries and the brachiocephalic artery. Proper inflation and engagement of the balloon 306 with the ascending aorta are indicated by a noticeable brightening of the first bright spot 322. The position of the catheter 300 and the inflation state of the balloon 306 can be monitored continuously throughout the surgery without the need for fluoroscopic or ultrasonic imaging techniques.

FIG 11 is a cutaway view of a patient's heart showing a double-balloon aortic cannula or catheter 400 for selective perfusion deployed within a patient's aorta. The catheter 400 has been configured for retrograde deployment in a patient's aorta via peripheral arterial access by percutaneous Seldinger technique or by an arterial cutdown of the femoral artery. Details of construction for this catheter, as well as other configurations for retrograde deployment via the subclavian or axillary artery or for antegrade deployment via direct central access into the ascending aorta, can be found in commonly owned, copending patent application 60/067,945.

For femoral artery deployment in adult human patients, the elongated flexible tubular shaft 402 of the catheter preferably has a length of approximately 60 to 120 cm, more preferably 70 to 90 cm, and an outer diameter of approximately 9 to 30 French (3.0-10 mm diameter), more preferably 12 to 18 French (4.0-6.0 mm diameter). For pediatric patients the diameter may be smaller. The tubular shaft 402 is precurved with an approximately J-shaped curve 404 that approximates the curve of the aortic arch. A first aortic occlusion balloon 406 with an expanded diameter of approximately 25 to 40 mm is mounted near the distal end of the tubular shaft 402. A second aortic occlusion balloon 426 with an expanded diameter of approximately 25 to 40 mm is mounted on the tubular shaft 402 proximal to the first aortic occlusion balloon 406 so that it is position within the descending aorta when the catheter 400 is deployed. The second balloon 426 may be a somewhat larger, elongated anchoring balloon that assists in anchoring the catheter 400 in position once deployed. A first illumination means 408 is located within the first balloon 406 and a second illumination means 410 is located on the tubular shaft 402 distal to the first balloon 406. The first and second illumination means 408, 410 are preferably positioned to emit a first and second beam of light approximately perpendicular to the plane of the J-shaped curve 404 so that the light beams will be visible on the anterior aspect of the ascending aorta when the catheter 400 is deployed. Additional illumination means may be located in the vicinity of the second balloon 426 if desired.

A first inflation fitting 416, such as a Luer fitting stopcock or the like, is provided at the proximal end of the catheter 400 for connection to a syringe or other balloon inflation device 430 for inflating the first balloon 406 through a first balloon inflation port 414 on the catheter shaft 402. A second inflation fitting 436, also a Luer fitting, stopcock or the like, is provided at the proximal end of the catheter 400 for connection to a second syringe or other balloon inflation device 432 for inflating the second balloon 426 through a second balloon inflation port 428 on the catheter shaft 402. A first perfusion fitting 418, which may be a Luer fitting, barb connector, a standard tapered perfusion fitting or the like, is provided for connection to a perfusion pump or the like for perfusing a cardioplegic agent or other fluids through a fluid lumen and out the distal port 412 on the catheter shaft 402.

A second perfusion fitting 446 is provided for connection to a perfusion pump or the like for perfusing the aortic arch vessels through a blood lumen and out one or more intermediate ports 442 on the catheter shaft 402 between the first and second balloons 406, 426 and are capable of providing flow necessary to support the metabolic demands of the cerebral circulation. A third perfusion fitting 448 is provided for connection to a perfusion pump or the like for perfusing the descending aorta through a blood lumen and out one or more proximal ports 444 on the catheter shaft 402 proximal to the second balloon 426 and are capable of providing the flow necessary to support the metabolic demands of the corporeal circulation.

The intermediate ports 442 are in fluid communication with a blood lumen and are sized and configured to provide a flow rate of 0.1 L/min to 3 L/min with a pressure drop between 0 mm Hg and 300 mm Hg, more preferably configured to provide 0.25 L/min to 2.5 L/min with a pressure drop between 0 mm Hg and 200 mm Hg, most preferably configured to provide 1 L/min to 2 L/min with a pressure drop between 0 mm Hg and 100 mm Hg.

The proximal ports 444 are in fluid communication with a blood lumen and are sized and configured to provide a flow rate of 0.5 L/min to 8 L/min with a pressure drop between 0 mm Hg and 300 mm Hg, more preferably configured to provide 2 L/min to 6 L/min with a pressure drop between 0 mm Hg and 200 mm Hg, most preferably configured to provide 3.00 L/min to 5.00 L/min with a pressure drop between 0 mm Hg and 100 mm Hg.

If required, a connector 422 is provided at the proximal end of the catheter 400 for connection to a light source 420, such as a xenon lamp, halogen lamp or a laser, or to an electrical power source, as appropriate. The first and second illumination means 408, 410 are used for positioning the catheter 400 and for monitoring the position and the inflation state of the first balloon 406 throughout the surgical procedure in much the same way as described above in connection with FIG 10.

FIG 12 is a cutaway view of a patient's heart showing a double-valve aortic catheter 500, similar to the catheter 200 described in connection with FIGS 6-8, deployed within a

patient's aorta. The catheter 500 has been configured for retrograde deployment in a patient's aorta via peripheral arterial access by percutaneous Seldinger technique or by an arterial cutdown of the femoral artery. Other modifications may be made to the catheter 500 for retrograde deployment via the subclavian or axillary artery or for antegrade deployment via direct central access into the ascending aorta. For femoral artery deployment in adult human patients, the elongated flexible tubular shaft 502 of the catheter preferably has a length of approximately 60 to 120 cm, more preferably 70 to 90 cm, and an outer diameter of approximately 9 to 28 French (3.0-9.3 mm diameter), more preferably 12 to 22 French (4.0-7.3 mm diameter). The tubular shaft 502 is precurved with an approximately J-shaped curve 504 that approximates the curve of the aortic arch. A first, antegrade external catheter valve 506 with an expanded diameter of approximately 25 to 40 mm is mounted near the distal end of the tubular shaft 502. A second, retrograde flow external catheter valve 526 with an expanded diameter of approximately 25 to 40 mm is mounted on the tubular shaft 502 proximal to the first valve 506 so that it is position within the descending aorta when the catheter 500 is deployed. A first illumination means 508 is located on the elongated tubular shaft 502 distal to the first valve 506 and one or more second illumination means 510 is located near the outer periphery of the first valve 506. The first and second illumination means 508, 510 are preferably positioned to emit a first and second beam of light approximately perpendicular to the plane of the J-shaped curve 504 so that the light beams will be visible on the anterior aspect of the ascending aorta when the catheter 500 is deployed.

A first actuation member 514, is provided at the proximal end of the catheter 500 for selectively deploying the first valve 506 and a second actuation member 516, is provided for selectively deploying the second valve 526. A first perfusion fitting 518, which may be a Luer fitting or a standard tapered perfusion fitting, is provided for connection to a perfusion pump or the like for perfusing a cardioplegic agent or other fluids through a distal port 512 on the catheter shaft 502. A second perfusion fitting 546 is provided for connection to a perfusion pump or the like for perfusing the aortic arch vessels through one or more intermediate ports 542 on the catheter shaft 502 between the first and second valves 506, 526. A third perfusion fitting 548 is provided for connection to a perfusion pump or the like for

perfusing the descending aorta through one or more proximal ports 544 on the catheter shaft 502 proximal to the second valve 526. If required, a connector 522 is provided at the proximal end of the catheter 500 for connection to a light source 520. such as a xenon lamp or a laser, or to an electrical power source, as appropriate.

The first and second illumination means 508, 510 are used for positioning the catheter 500 and for monitoring the position and the expansion state of the first valve 506 throughout the surgical procedure in much the same way as described above in connection with FIG 10.

FIG 13 is a cutaway view of a patient's heart showing a two-lumen, double-balloon venous drainage catheter or cannula 600 deployed within a patient's inferior and superior vena cava. The two-lumen, double-balloon venous drainage cannula 600 can be used for performing standard cardiopulmonary bypass by open-chest, cutdown or percutaneous techniques or for performing isolated segmental perfusion as described in commonly owned, copending patent application 60/084,835. The cannula 600 has a flexible elongated tubular shaft 602 made of a flexible polymer or elastomer or a reinforced polymer composite. The elongated tubular shaft 602 has a first venous drainage lumen 630, a second venous drainage lumen 632 and one or more balloon inflation lumens. When configured for peripheral deployment, such as via the femoral vein or jugular vein, in adult human patients, the elongated tubular shaft 602 has a length that is preferably from approximately 15 to 90 cm, more preferably from approximately 50 to 70 cm, and an outer diameter that is preferably from approximately 12 to 32 French (4-10.7 mm diameter). more preferably from approximately 18 to 24 French (6-8 mm diameter).

A first vena cava occlusion balloon 604 with an expanded diameter of approximately 10 to 50 mm is mounted on the tubular shaft 602. An optional second vena cava occlusion balloon 606 with an expanded diameter of approximately 10 to 50 mm is mounted on the tubular shaft 602 distal to the first balloon 604. A first illumination means 608 is located within or in the vicinity of the first balloon 604 and a second illumination means 610 is located near the distal end of the cannula 600 or within or in the vicinity of the second balloon 606. The first and second illumination means 608, 610 are preferably positioned to

emit a first and second beam of light approximately perpendicular to the tubular shaft 602 so that the light beams will be visible on the anterior aspect of the inferior and superior vena cava when the cannula 600 is deployed.

A first inflation fitting 616, such as a Luer fitting or the like, is provided at the proximal end of the cannula 600 for connection to a syringe or other balloon inflation device for inflating the first balloon 604 through a first balloon inflation port 614 on the catheter shaft 602. Optionally, the cannula 600 may include a third and fourth illumination means for monitoring of the balloons 604 and 606 as described above. An optional second inflation fitting 618, also a Luer fitting or the like, is provided at the proximal end of the cannula 600 for connection to a second syringe or other balloon inflation device for inflating the optional second balloon 606 through a second balloon inflation port 620 on the catheter shaft 602. A first drainage fitting 622, which may be a standard barb fitting, a Luer fitting or the like, is provided for connecting the first venous drainage lumen 630 to a drainage reservoir, vacuum system or the like for draining venous blood or other fluids through one or more distal drainage ports 634 on the catheter shaft 602. A second drainage fitting 624, also a standard barb fitting, a Luer fitting or the like, is provided for connecting the second venous drainage lumen 632 to a drainage reservoir, vacuum system or the like for draining venous blood or other fluids through one or more proximal drainage ports 636 on the catheter shaft 602. If required, a connector 638 is provided at the proximal end of the cannula 600 for connection to a light source 640, such as a xenon lamp, halogen lamp or a laser, or to an electrical power source, as appropriate.

Other configurations of venous catheters or cannulas for performing isolated segmental perfusion and suitable for combination with illumination means for performing blood vessel tissue transillumination according to the present invention can be found in commonly owned, copending patent application 60/084,835, which has previously been incorporated by reference.

FIG 14 is an anterior view of the patient's heart with the venous cannula 600 of FIG 13 deployed within the patient's inferior and superior vena cava. The patient's heart has been

exposed via median sternotomy, a lateral thoracotomy or mini-thoracotomy or by port-access or thoracoscopic techniques. The venous cannula 600 is not visible, except for the two bright spots 642, 644 on the anterior surface of the inferior and superior vena cava created by the first and second illumination means 608, 610. The position of the cannula 600, and optionally the inflation state of the balloons 604, 606, can be determined by the location and intensity of the two bright spots 642, 644 without the need for fluoroscopic or ultrasonic imaging techniques.

FIG 15 is a cutaway view of a patient's heart showing a single-lumen, two-stage venous drainage catheter or cannula 700 deployed within a patient's inferior and superior vena cava. The single-lumen, two-stage venous drainage cannula 600 is configured for use in standard cardiopulmonary bypass by open-chest or percutaneous techniques. The cannula 700 has a flexible elongated tubular shaft 702 made of a flexible polymer or elastomer or a reinforced polymer composite. The elongated tubular shaft 702 has a single venous drainage lumen 704 that connects to a series of distal drainage ports 706 and proximal drainage ports 708 for draining venous blood or other fluids from the patient's inferior and superior vena cava. The elongated tubular shaft 702 may be tapered along an intermediate portion 712 to balance fluid flow between the distal drainage ports 706 and the proximal drainage ports 708. A drainage fitting 710, which may be a standard barb fitting, a Luer fitting or the like, is provided on the proximal end of the cannula 700 for connecting the venous drainage lumen 704 to a drainage reservoir, vacuum system or the like. When configured for peripheral deployment, such as via the femoral vein or jugular vein, in adult human patients, the elongated tubular shaft 702 has a length that is preferably from approximately 40 to 90 cm, more preferably from approximately 50 to 70 cm, and an outer diameter that is preferably from approximately 12 to 32 French (4-10.7 mm diameter), more preferably from approximately 18 to 24 French (6-8 mm diameter).

A first illumination means 714 is located on the tubular shaft 702 in the vicinity of the proximal drainage ports 708 and a second illumination means 716 is located near the distal end of the cannula 700 or within the vicinity of the distal drainage ports 706. The first and second illumination means 714, 716 are preferably positioned to emit a first and second beam

of light approximately perpendicular to the tubular shaft 702 so that the light beams will be visible on the anterior aspect of the inferior and superior vena cava when the cannula 700 is deployed. If required, a connector 718 is provided at the proximal end of the cannula 700 for connection to a light source 720, such as a xenon lamp, halogen lamp or a laser, or to an electrical power source, as appropriate.

The first and second illumination means 714, 716 are used for positioning the venous cannula 700 and for monitoring the position of the proximal and distal drainage ports 708, 706 throughout the surgical procedure in much the same way as described above in connection with FIG 14.

FIG 16 is a cross section of a catheter or cannula 800 showing an alternate illumination means for tissue transillumination of a blood vessel according to the present invention. The cannula 800 is made with an elongated tubular shaft 802 having a proximal end 804 and a distal end 806. The cannula 800 may have one or more inflatable balloons, selectively expandable external catheter valves or other expandable flow control members 808 and one or more perfusion or drainage lumens 810, as described above in connection with each of the described embodiments. The walls 812 of the elongated tubular shaft 802 of the cannula 800 are made of an optically clear, flexible material, preferably a flexible polymer or elastomer, that acts as an optical waveguide. The proximal end 804 of cannula 800 is coupled to a light source 822 and the walls 812 of the elongated tubular shaft 802 direct the light from the proximal end 804 to the distal end 806 of the cannula 800. At or near the distal end 806 of the cannula 800 is a reflective surface 814 that directs a light beam 816 approximately perpendicular or at another chosen angle to the elongated tubular shaft 802. The reflective surface 814 may be embedded into the wall 812 of the elongated tubular shaft 802 or it may be applied as a reflective coating onto a beveled distal end 806 of the cannula 800. Optionally, the cannula 800 may include one or more intermediate reflective surfaces 818 along the length of the elongated tubular shaft 802. For example, an intermediate reflective surface 818 may be placed within or in the vicinity of one or more of the expandable flow control members 808, or surface cuts with embedded reflective surfaces or surface cuts which create a lossy surface for light to escape. to the elongated tubular shaft

802. The intermediate reflective surfaces 818 may be fully reflective or partially reflective and sized to direct a fractional portion of the light passing through the wall 812 into a light beam 820 approximately perpendicular to the elongated tubular shaft 802. Alternatively, refractive elements, such as prisms or lenses, may be used in place of one or more of the reflective surfaces for directing one or more beams of light in a chosen direction relative to the elongated tubular shaft 802.

FIG 17 is a cross section of a catheter or cannula 830 showing another alternate illumination means for tissue transillumination of a blood vessel. The cannula 830 is made with an elongated tubular shaft 832 having a proximal end 834 and a distal end 836. The cannula 830 may have one or more inflatable balloons, selectively expandable external catheter valves or other expandable flow control members (not shown) and one or more perfusion or drainage lumens 838, as described above. The walls 840 of the elongated tubular shaft 832 of the cannula 830 are made of an optically clear, flexible material, preferably a flexible polymer or elastomer, that acts as an optical waveguide. The proximal end 834 of cannula 830 is coupled to a light source 822 and the walls 840 of the elongated tubular shaft 832 direct the light from the proximal end 834 to the distal end 836 of the cannula 830. At or near the distal end 836 of the cannula 830 is a region that has been embedded with a multiplicity of reflective particles 842 that direct a diffuse light beam 844 from the elongated tubular shaft 832 to create a bright glow around the cannula 830. Optionally, the cannula 830 may include one or more intermediate regions embedded with a multiplicity of reflective particles 846 along the length of the elongated tubular shaft 832, for example within or in the vicinity of one or more expandable flow control members. The size and density of the reflective particles 846 is selected to direct a fractional portion of the light passing through the wall 832 into a secondary diffuse light beam 848. Alternatively, refractive particles or fluorescent dyes or materials (e.g. SURLYN ionomer resin), or other light reflective or diffusing elements, may be used in place of the reflective particles for creating one or more diffuse beams of light.

FIG 18 is a cross section of a catheter or cannula 850 showing another alternate illumination means for tissue transillumination of a blood vessel. The cannula 850 is made

with an elongated tubular shaft 852 having a proximal end 854 and a distal end 856. The cannula 850 may have one or more inflatable balloons, selectively expandable external catheter valves or other expandable flow control members (not shown) and one or more perfusion or drainage lumens 858, as described above. The walls 860 of the elongated tubular shaft 852 of the cannula 850 are made of a flexible material, preferably a flexible polymer or elastomer. In use, the lumen 858 is filled with an optically clear fluid 862, for example saline solution, crystalloid cardioplegia solution, a water and ethanol mixture, or other clear liquid. The internal surface of the lumen 858 is made reflective. This can be accomplished by choosing a material for the walls 860 that has a refractive index significantly different from that of the clear fluid 862. One working combination uses a fluoropolymer, such as polytetrafluoroethylene. as the material of the cannula walls 860 and a water and ethanol mixture as the clear fluid 862. Alternatively, the internal surface of the lumen 858 can be coated with a reflective coating, which gives much greater latitude in choosing the compositions of the cannula walls 860 and the clear fluid 862. The fluid filled 862 internal lumen 858 will act as an optical waveguide to direct light from a light source 822 at the proximal end 854 of the cannula 850 to the distal end 856 of the cannula 850. At or near the distal end 856 of the cannula 850 is a reflective surface 866 that direct a light beam 864 away from the elongated tubular shaft 852 at a chosen angle. Optionally, the cannula 850 may include one or more intermediate reflective surfaces within the same lumen or in different lumens to create one or more secondary light beams.

FIG 19 is a cross section of a catheter or cannula 870 having a separate transillumination device 880 that is insertable into or through a lumen of the cannula 870. The cannula 870 is made with an elongated tubular shaft 872 having a proximal end 874 and a distal end 876. The cannula 870 may have one or more inflatable balloons, selectively expandable external catheter valves or other expandable flow control members (not shown) and one or more perfusion or drainage lumens 878, as described above in connection with each of the described embodiments. Optionally, the cannula 870 may also have one or more apertures or optically clear windows 868 at intermediate points along the elongated tubular shaft 872 or the entire elongated tubular shaft 872 may be made of an optically clear material.

The transillumination device 880 has an elongated flexible body 882 having a proximal end 884 and a distal end 886. The elongated flexible body 882 is sized to fit within one of the lumens 878 of the cannula 870 and has a diameter that is preferably between approximately 0.25 and 2 mm, more preferably between approximately 0.5 and 1 mm. The length of the elongated flexible body 882 may be the same or somewhat less than the length of the elongated tubular shaft 872 of the cannula 870 so that it will act as an internal stylet within the cannula 870. or it may be somewhat greater than the length of the elongated tubular shaft 872 so that it can be used as a guidewire for guidance and manipulation of the cannula 870. The transillumination device 880 includes at least one illumination means 888 for emitting a beam of light 890 from the device 880, preferably near the distal end 886 of the elongated flexible body 882. Additional illumination means 892 may be provided along the length of the elongated flexible body 882. The illumination means 888, 892 may be positioned to coincide with any balloons, apertures or optically clear windows 868 present on the elongated tubular shaft 872 of the cannula 870. The illumination means 888, 892 may be provided in the form of optical fibers, light emitting diodes, laser diodes, incandescent, fluorescent or chemoluminescent lights or other known light emitting technologies. The illumination means may emit a diffuse glow of light or a focused or shaped beam of light. If required, an electrical or optical connector is provided at the proximal end 884 of the elongated flexible body 882 for connection to a light source or to an electrical power source 894, as appropriate.

The elongated flexible body 882 of the transillumination device 880 may be constructed of many possible materials. It may be constructed of a flexible polymer or elastomer, a braided or coiled wire or filament reinforced polymer composite, a metal coil, a flexible metallic tube or wire, with one or more optical fibers or electrical wires running through it, as appropriate. Alternatively, one or more optical fibers and their cladding may constitute the bulk of the elongated flexible body 882. The elongated flexible body 882 may have regions of different flexibility along its length. Coatings may be added to the exterior of the elongated flexible body 882 for smoothness, lubricity or biocompatibility such a MEDI-COAT, SLIP-COAT or ECHO-COAT by STS Biopolymers, Henrietta, New York.

If the transillumination device 880 is intended for use as an internal stylet within the cannula 870, it may also include a mechanical connector, for example a Luer fitting, for removably attaching the transillumination device 880 to the cannula 870, preferably with the illumination means 888, 892 in proper registration with the balloons or other features of the cannula 870. If the transillumination device 880 is intended for use as a guidewire, it may be preferable to use illumination means 888, 892 in the form of light emitting diodes or laser diodes with an internal power source, such as a miniature battery, so that there are no fittings or connectors on the exterior of the device that would inhibit catheter exchanges or other guidewire maneuvers. In this case, the light emitting diodes or laser diodes are preferably activated by a switch that does not add to the bulk of the elongated flexible body 882. For example, such a switch could be activated by bending, squeezing or twisting the elongated flexible body 882 or by applying an external force, such as with a magnet. If the transillumination device 880 is intended for one-time use only, the switch need not provide a means for deactivating the illumination means 888, 892. For example, the transillumination device 880 could be configured so that the illumination means 888, 892 is activated upon removal of the device 880 from its protective packaging and is discarded at the end of the procedure without the need to deactivate the illumination means 888, 892. If desired external markings may be provided on the elongated flexible body 882 of the transillumination device 880 to align the illumination means 888, 892 with the balloons or other features of the cannula 870. In addition, the cannula 870 may be provided with a temporary connection device, such as a Touhy-Borst fitting or other compression fitting, for temporarily attaching the transillumination device 880 to the cannula 870, without interfering with catheter exchanges or other guidewire maneuvers.

In use, the transillumination device 880 is intended to be illuminated and inserted into the lumen 878 of the cannula 870 before insertion of the cannula 870 into the patient's blood vessels. The illumination means 888, 892 are used for positioning the cannula 870 in much the same way as described above in connection with FIGS 10 and 14. The transillumination device 880 may then be withdrawn from the cannula 870 to provide additional lumen space for perfusion or drainage. Alternatively, the transillumination device 880 may be left within

the cannula 870 or it may be periodically reinserted for continuously or intermittently monitoring the position of the cannula 870 throughout the surgical procedure.

Each of the catheters, cannulas and transillumination devices described herein is preferably supplied to the end user sterilized and in protective packaging with appropriate instructions describing the method of use. In addition, they may be included in procedural kits with guidewires, connecting tubes, fittings and other catheters, cannulas or surgical devices intended for a particular surgical procedure. Each of the described catheters, cannulas and transillumination devices may be constructed for repeat use or for one-time use only.

Other configurations and modifications of the described catheters, cannulas and transillumination devices are possible within the scope of the present invention. For example, the described elements of the various embodiments of the invention can be combined together in any number of operative combinations and subcombinations. All operative combinations and subcombinations of the disclosed elements are deemed to be within the scope of the disclosure as if they had been disclosed explicitly. One possible modification of the present invention would be to utilize an invisible light source, such as an ultraviolet, infrared or near-infrared laser diode, in place of or in addition to the visible light sources used in the embodiments described. Special viewing or imaging equipment, such as night vision goggles or an ultraviolet or infrared viewing camera or endoscope, would be used to observe the position of the catheter or cannula. Such ultraviolet or infrared viewing or imaging equipment can be less expensive and less cumbersome than expensive fluoroscopic and ultrasonic imaging equipment. The use of invisible frequencies of light may have additional advantages in the present invention. such as improved tissue penetration, which may allow visualization of the catheter or cannula position from the exterior without the necessity of opening the patient's chest. Special imaging devices may also allow easier visualization of the transillumination device in a brightly lit environment because the invisible frequencies of light will provide a contrast to the visible light used to illuminate the operating field. Other possible modifications would include the addition of radiopaque and/or sonoreflective markers on the catheter or cannula to improve visualization using conventional fluoroscopic and ultrasonic imaging equipment as an adjunct to tissue transillumination.

Modifications and additions to the described methods are also possible within the scope of the present invention. For example the tissue transillumination provided by the illumination means of the catheters, cannulas and transillumination devices can be used for detecting plaques and calcifications within a blood vessel, such as the ascending aorta and aortic arch. The information derived can be used for choosing a cannulation or anastomosis site on the blood vessel or for diagnosing vascular disease and choosing appropriate therapy.

**WHAT IS CLAIMED IS:**

1. A cannula for cardiopulmonary bypass comprising:

an elongated tubular body configured for placement within a blood vessel of a patient;

a blood flow lumen within the elongated tubular body sized and dimensioned to allow sufficient blood flow to meet the metabolic demand of an organ subsystem that is being supplied with said blood; and

an illumination means positioned on the elongated tubular body for directing light through a blood vessel wall.

2. The cannula for cardiopulmonary bypass of claim 1, wherein the blood vessel comprises an artery.

3. The cannula for cardiopulmonary bypass of claim 2, wherein the blood vessel comprises an aorta.

4. The cannula for cardiopulmonary bypass of claim 2, wherein the artery comprises a femoral artery.

5. The cannula for cardiopulmonary bypass of claim 2, wherein the blood vessel wall comprises an aortic wall.

6. The cannula for cardiopulmonary bypass of claim 1, wherein the blood vessel is a vein.

7. The cannula for cardiopulmonary bypass of claim 6, wherein the vein comprises a femoral vein.

8. The cannula for cardiopulmonary bypass of claim 6, wherein the vein comprises a jugular vein.

9. The cannula for cardiopulmonary bypass of claim 6, wherein the vein comprises a vena cava.

10. The cannula for cardiopulmonary bypass of claim 6, wherein the blood vessel wall comprises a vena cava wall.

11. The cannula for cardiopulmonary bypass of claim 1, wherein the illumination means comprises a light emitting diode.

12. The cannula for cardiopulmonary bypass of claim 1, wherein the illumination means comprises a laser diode.

13. The cannula for cardiopulmonary bypass of claim 1, wherein the illumination means comprises a light transmitting optical fiber.

14. The cannula for cardiopulmonary bypass of claim 1, wherein the illumination means comprises a light transmitting optical waveguide.

15. The cannula for cardiopulmonary bypass of claim 1, wherein the illumination means emits a beam of visible light.

16. The cannula for cardiopulmonary bypass of claim 1, wherein the illumination means emits a beam of invisible light.

17. The cannula for cardiopulmonary bypass of claim 16, further comprising an imaging means for viewing the beam of invisible light.

18. The cannula for cardiopulmonary bypass of claim 1, wherein the illumination means emits a beam of infrared light.

19. The cannula for cardiopulmonary bypass of claim 18, further comprising an imaging means for viewing the infrared light.

20. The cannula for cardiopulmonary bypass of claim 1, further comprising an expandable external flow control member mounted on the elongated tubular body.

21. The cannula for cardiopulmonary bypass of claim 20, further comprising a second expandable external flow control member mounted on the elongated tubular body.

22. The cannula for cardiopulmonary bypass of claim 1, further comprising a second blood flow lumen within the elongated tubular body.

23. The cannula for cardiopulmonary bypass of claim 22, wherein the blood flow lumen has a first outlet port and the second blood flow lumen has a second outlet port, the first outlet port and the second outlet port being spaced apart longitudinally along the elongated tubular body.

24. The cannula for cardiopulmonary bypass of claim 23, further comprising an expandable external flow control member mounted on the elongated tubular body between the first outlet port and the second outlet port.

25. The cannula for cardiopulmonary bypass of claim 24, further comprising a second expandable external flow control member mounted on the elongated tubular body.

26. The cannula for cardiopulmonary bypass of claim 1, further comprising a second illumination means mounted on the elongated tubular body.

27. The cannula for cardiopulmonary bypass of claim 1 or 26, wherein the illumination means is permanently mounted on the elongated tubular body.

28. The cannula for cardiopulmonary bypass of claim 1 or 26, wherein the illumination means is mounted on an elongated flexible body removably insertable into the elongated tubular body.

29. An aortic catheter apparatus comprising:

an elongated catheter shaft configured for introduction into a lumen of an aorta of a patient;

an aortic occlusion means mounted on the catheter shaft for selectively occluding the lumen of the aorta; and

a first light emitting means positioned on the catheter for emitting a beam of light through a wall of the aorta and a second light emitting means positioned to emit light from said occlusion means.

30. The aortic catheter apparatus of claim 29, wherein the light emitting means emits a beam of light approximately perpendicularly to the catheter shaft.

31. The aortic catheter apparatus of claim 29, wherein the light emitting means comprises a light emitting diode.

32. The aortic catheter apparatus of claim 29, wherein the light emitting means comprises a laser diode.

33. The aortic catheter apparatus of claim 29, wherein the light emitting means comprises a light transmitting optical fiber having a light emitting distal tip.

34. The aortic catheter apparatus of claim 29, wherein the light emitting means comprises a light transmitting optical waveguide having at least one light emitting portion.

35. The aortic catheter apparatus of claim 29, wherein the light emitting means emits a visible beam of light.

36. The aortic catheter apparatus of claim 29, wherein the light emitting means emits an infrared or near infrared beam of light.

37. The aortic catheter apparatus of claim 36, further comprising an infrared or near infrared light detecting means.

38. The aortic catheter apparatus of claim 36, further comprising an infrared or near infrared light imaging means.

39. The aortic catheter apparatus of claim 29, wherein the aortic occlusion means comprises an inflatable balloon.

40. The aortic catheter apparatus of claim 39, wherein the light emitting means is interior to the inflatable balloon.

41. The aortic catheter apparatus of claim 29, wherein the aortic occlusion means comprises a deployable valve mounted external to the catheter shaft.

42. The aortic catheter apparatus of claim 41, wherein the light emitting means is mounted on the valve.

43. The aortic catheter apparatus of claim 42, further comprising a second light emitting means mounted on the catheter shaft.

44. The aortic catheter apparatus of claim 29, further comprising a second aortic occlusion means mounted on the catheter shaft for selectively occluding the lumen of the aorta.

45. The aortic catheter apparatus of claim 29 or 44, further comprising at least one perfusion lumen within the elongated catheter shaft.

46. The aortic catheter apparatus of claim 29 or 44, further comprising two perfusion lumens within the elongated catheter shaft.

47. The aortic catheter apparatus of claim 29 or 44, further comprising three perfusion lumens within the elongated catheter shaft.

48. The aortic catheter apparatus of claim 29, wherein the illumination means is permanently mounted on the elongated catheter shaft.

49. The aortic catheter apparatus of claim 29, wherein the illumination means is mounted on an elongated flexible body removably insertable into the elongated catheter shaft.

50. A catheter localization system comprising:

a catheter comprising an elongated catheter shaft configured for introduction into a lumen of a blood vessel within a body cavity of a patient, and a light emitting means mounted on the catheter shaft for emitting a beam of light through a wall of the blood vessel; and

a visualization means for visualizing the light beam exterior to the blood vessel within the body cavity of the patient.

51. The catheter localization system of claim 50, wherein the visualization means comprises a surgical cannula introduced into the body cavity of the patient through an exterior surface of the patient or through an incision into the body cavity of the patient.

52. The catheter localization system of claim 50, wherein the visualization means comprises an endoscope introduced into the body cavity of the patient through an exterior surface of the patient.

53. The catheter localization system of claim 50, wherein the visualization means comprises a video endoscope introduced into the body cavity of the patient through an exterior surface of the patient.

54. The catheter localization system of claim 50, wherein the visualization means comprises an infrared or near infrared light imaging means.

55. The catheter localization system of claim 50, wherein the blood vessel is an aorta.

56. The catheter localization system of claim 50, wherein the blood vessel is an inferior vena cava.

57. The catheter localization system of claim 50, wherein the blood vessel is a superior vena cava.

58. The catheter localization system of claim 50, wherein the blood vessel is a right atrium.

59. The catheter localization system of claim 50, wherein the blood vessel is a coronary sinus.

60. The catheter localization system of claim 50, further comprising a blood vessel occlusion means mounted on the catheter shaft for selectively occluding the lumen of the blood vessel.

61. The catheter localization system of claim 50, further comprising a first blood vessel occlusion means and a second blood vessel occlusion means mounted on the catheter shaft for selectively occluding the lumen of the blood vessel.

62. The catheter localization system of claim 50, 60 or 61, wherein the elongated catheter shaft comprises at least one drainage lumen.

63. The catheter localization system of claim 50, 60 or 61, wherein the body cavity is a substantially intact thorax of a human patient.

64. A method of catheterization or cannulation comprising:

inserting a catheter or cannula into a great vessel of a patient's circulatory system;

directing a light beam from the catheter or cannula through a wall of the great vessel; and

visualizing the light beam on the exterior of the great vessel wall.

65. The method of claim 64, wherein the great vessel is an aorta.

66. The method of claim 64, wherein the great vessel is a vena cava.

67. The method of claim 64, 65 or 66, wherein the great vessel is visualized within a substantially intact thorax of a human patient.

68. The method of claim 64, further comprising occluding the great vessel.

69. The method of claim 64, 65 or 66, further comprising perfusing the great vessel.

70. The method of claim 64, 65 or 66, further comprising draining the great vessel.

71. A venous drainage cannula comprising:

an elongated tubular body;

a venous drainage lumen within said elongated tubular body; and

an illumination means for emitting a beam of light through a wall of a blood vessel.

72. The venous drainage cannula of claim 71, further comprising occlusion means.

73. The venous drainage cannula of claim 72, further comprising a second occlusion means.

74. The venous drainage cannula of claim 71, further comprising a second illumination means.

75. The venous drainage cannula of claim 71, further comprising a second venous drainage lumen within said elongated catheter body.

76. The venous drainage cannula of claim 71, wherein the venous drainage lumen is sized and configured to drain the superior vena cava.

77. The venous drainage cannula of claim 71, wherein the venous drainage lumen is sized and configured to drain the inferior vena cava.

78. The venous drainage cannula of claim 71, wherein the venous drainage lumen is sized and configured to drain both the superior vena cava and the inferior vena cava.

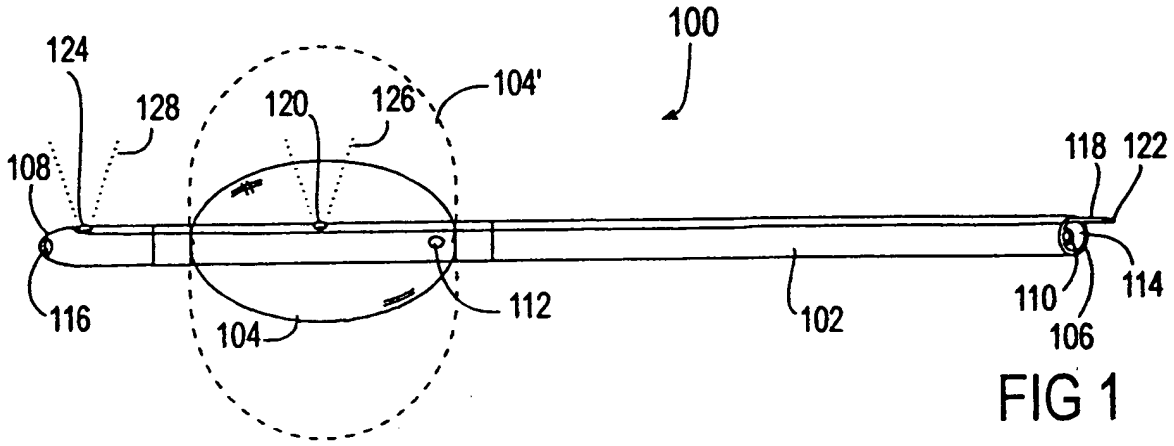


FIG 1

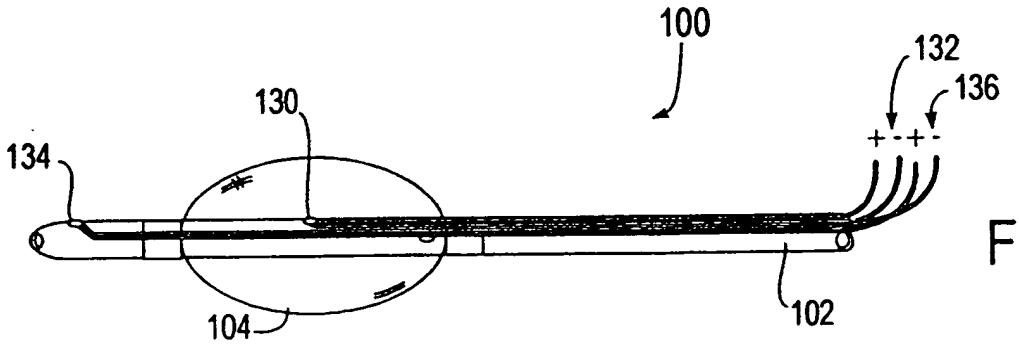


FIG 2

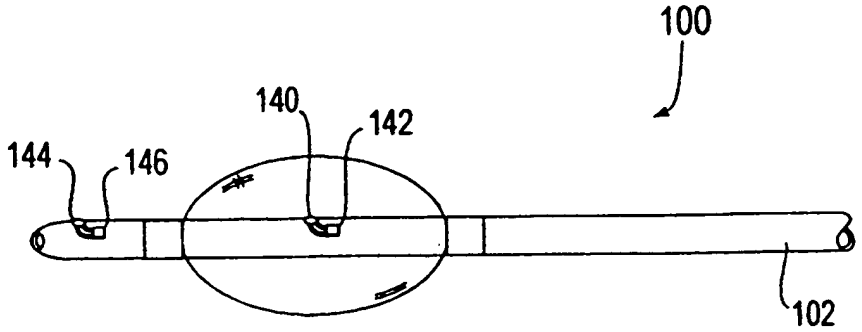


FIG 3

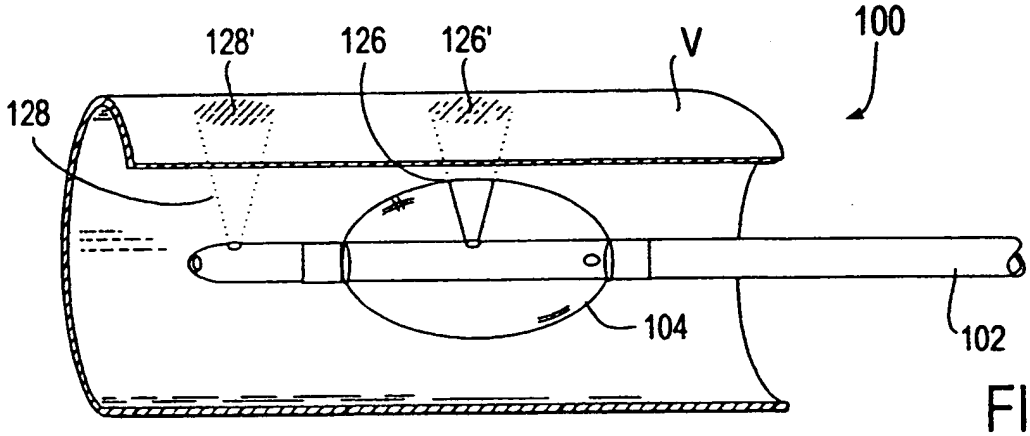


FIG 4

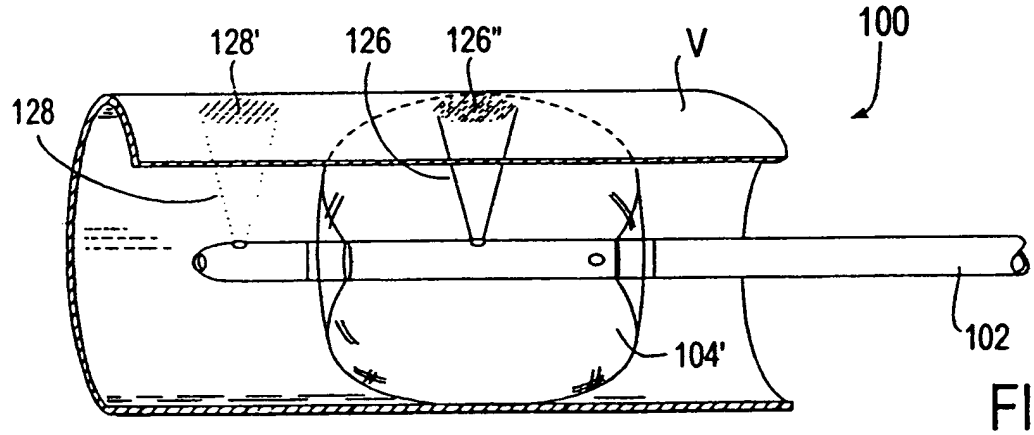


FIG 5

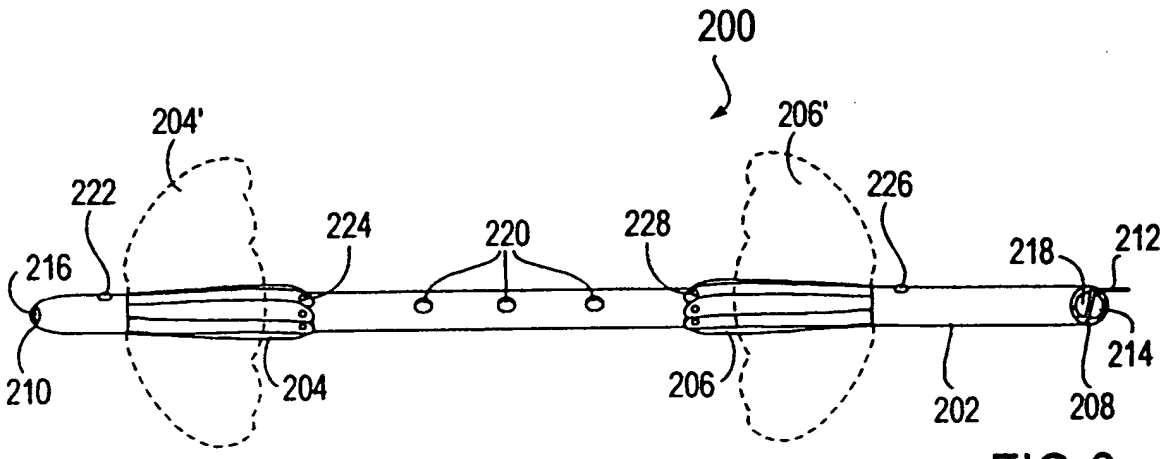


FIG 6

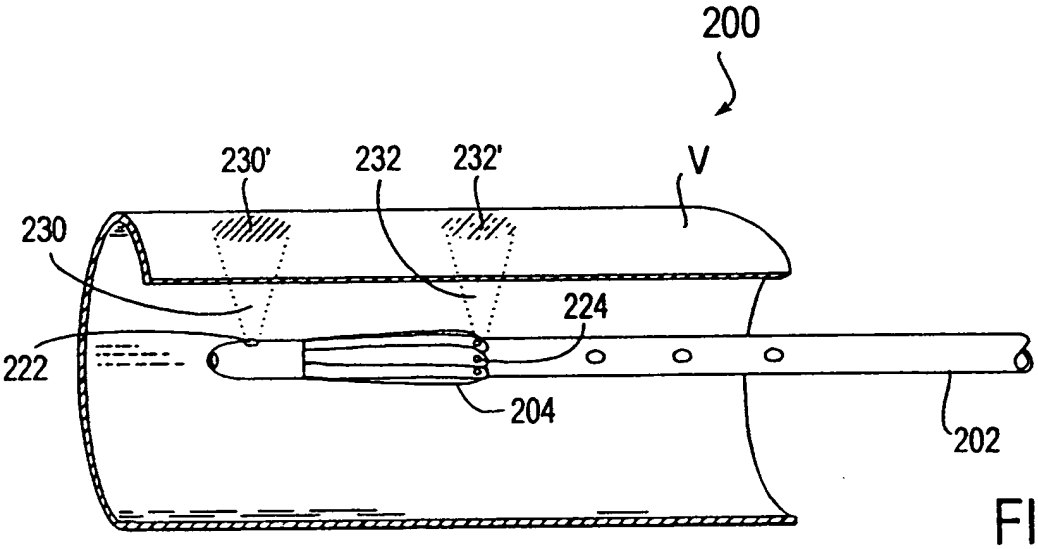


FIG 7

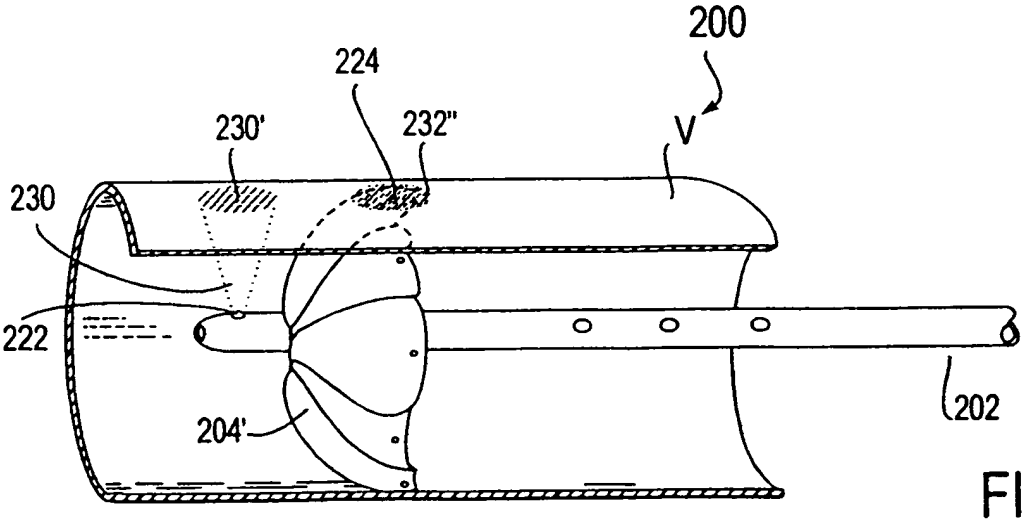


FIG 8

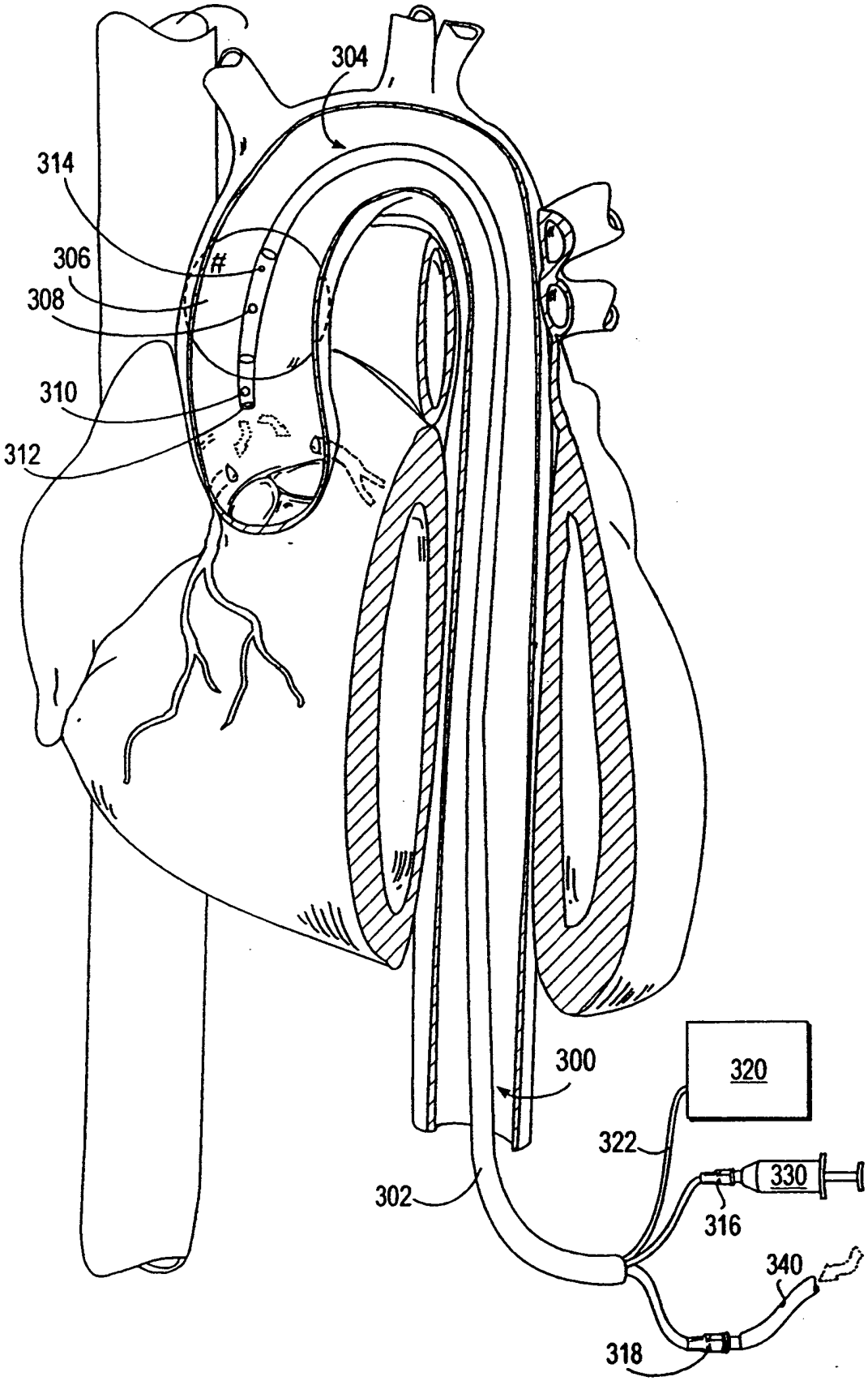


FIG 9

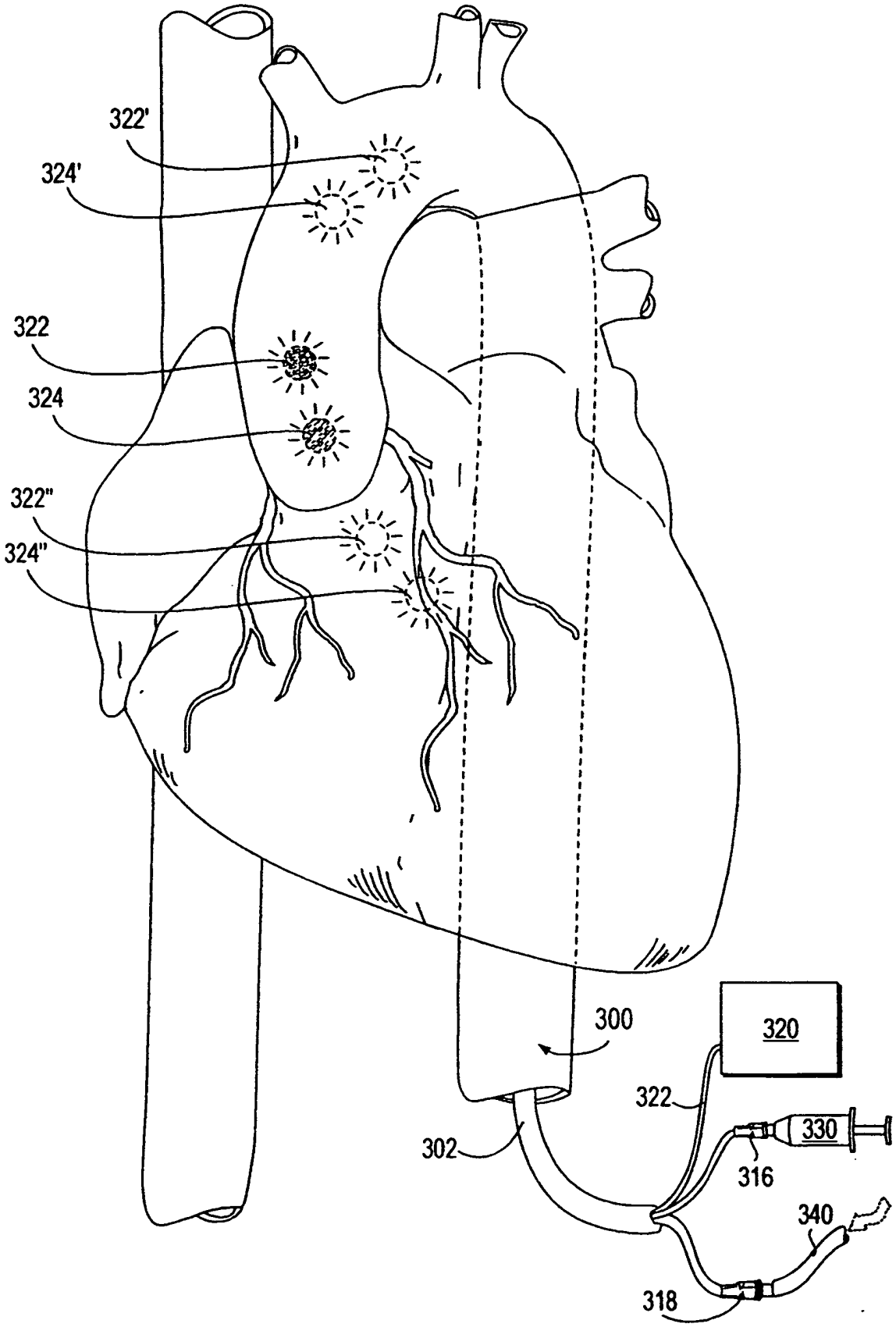


FIG 10

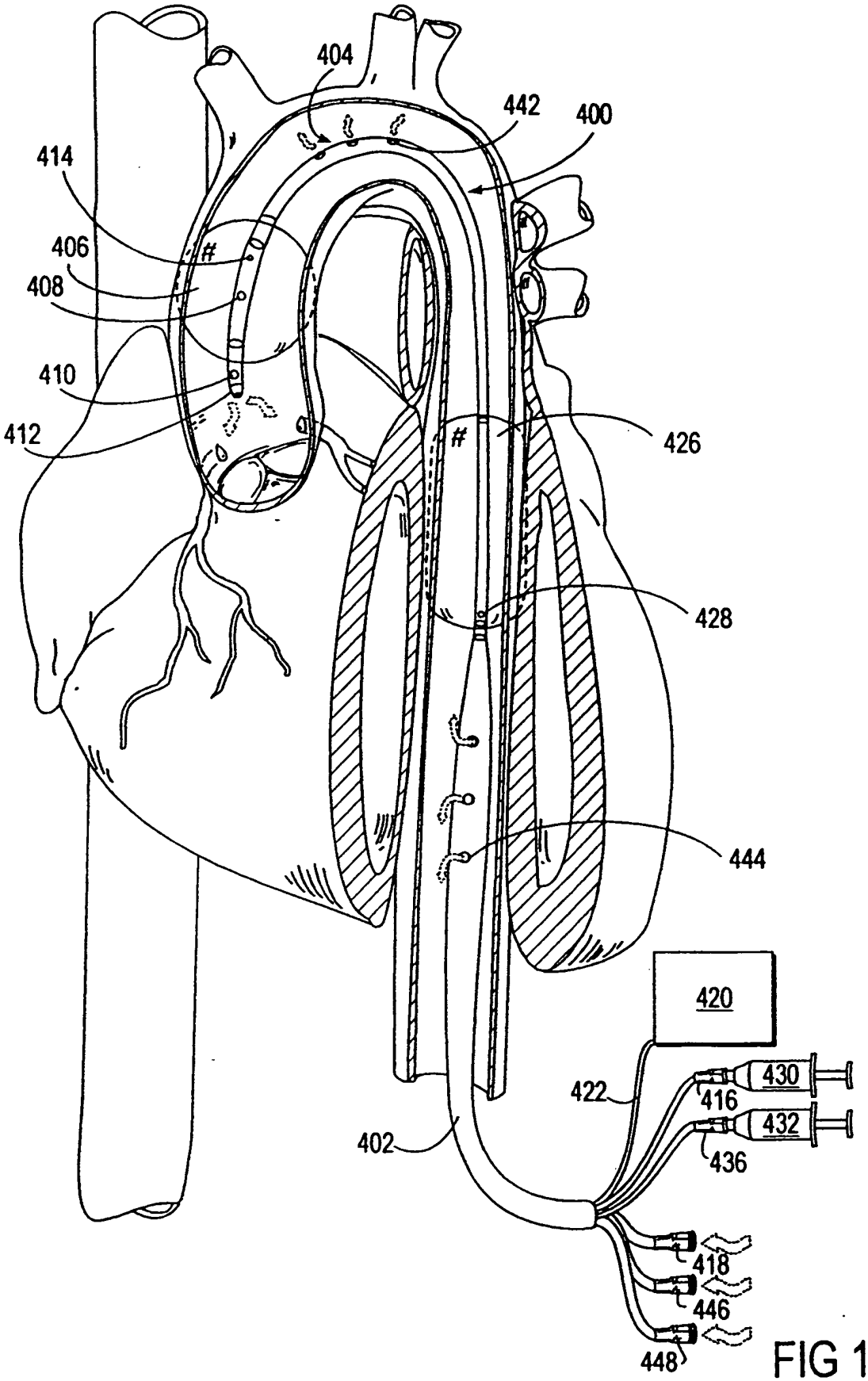
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FIG 11

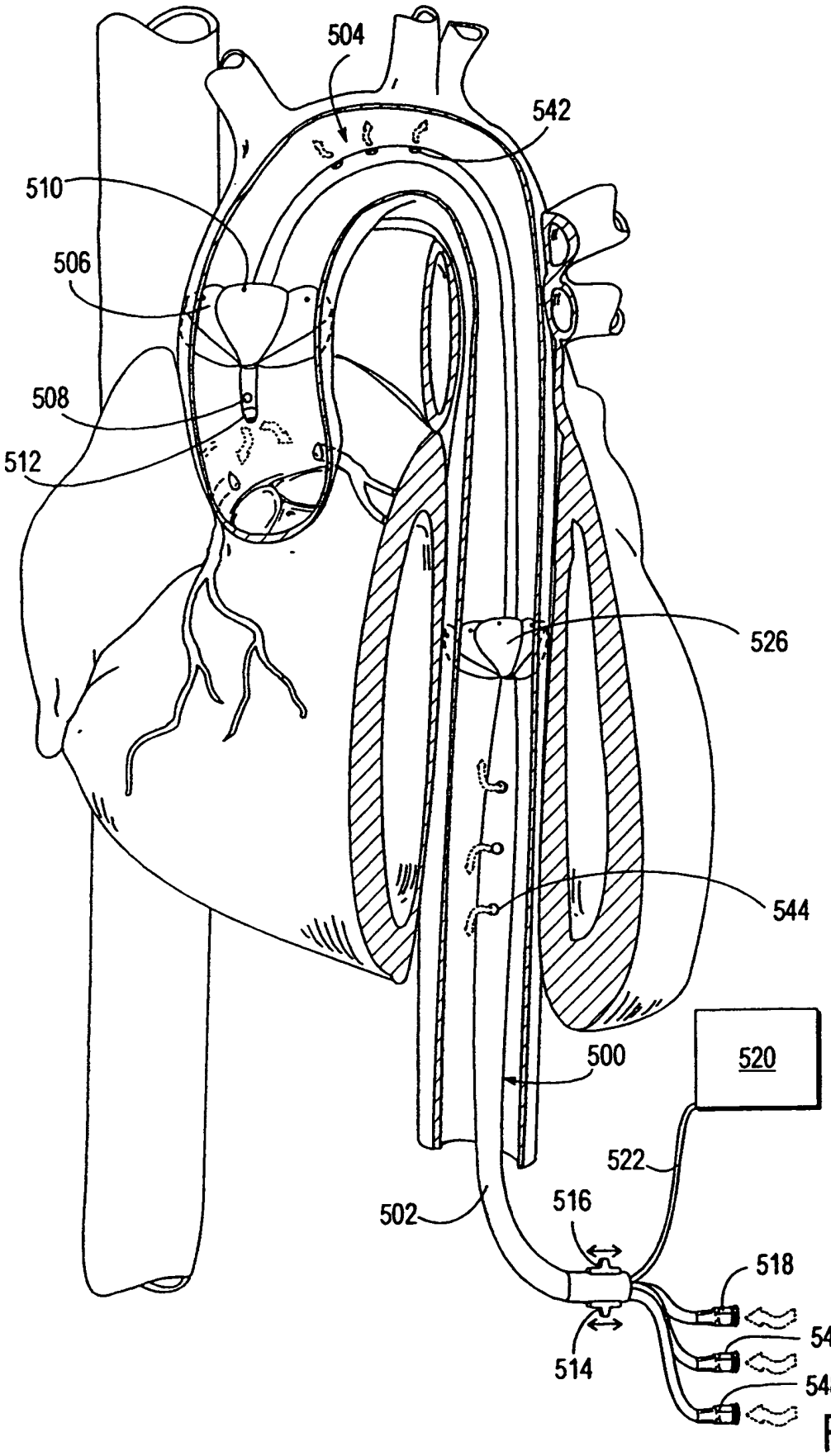
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FIG 12

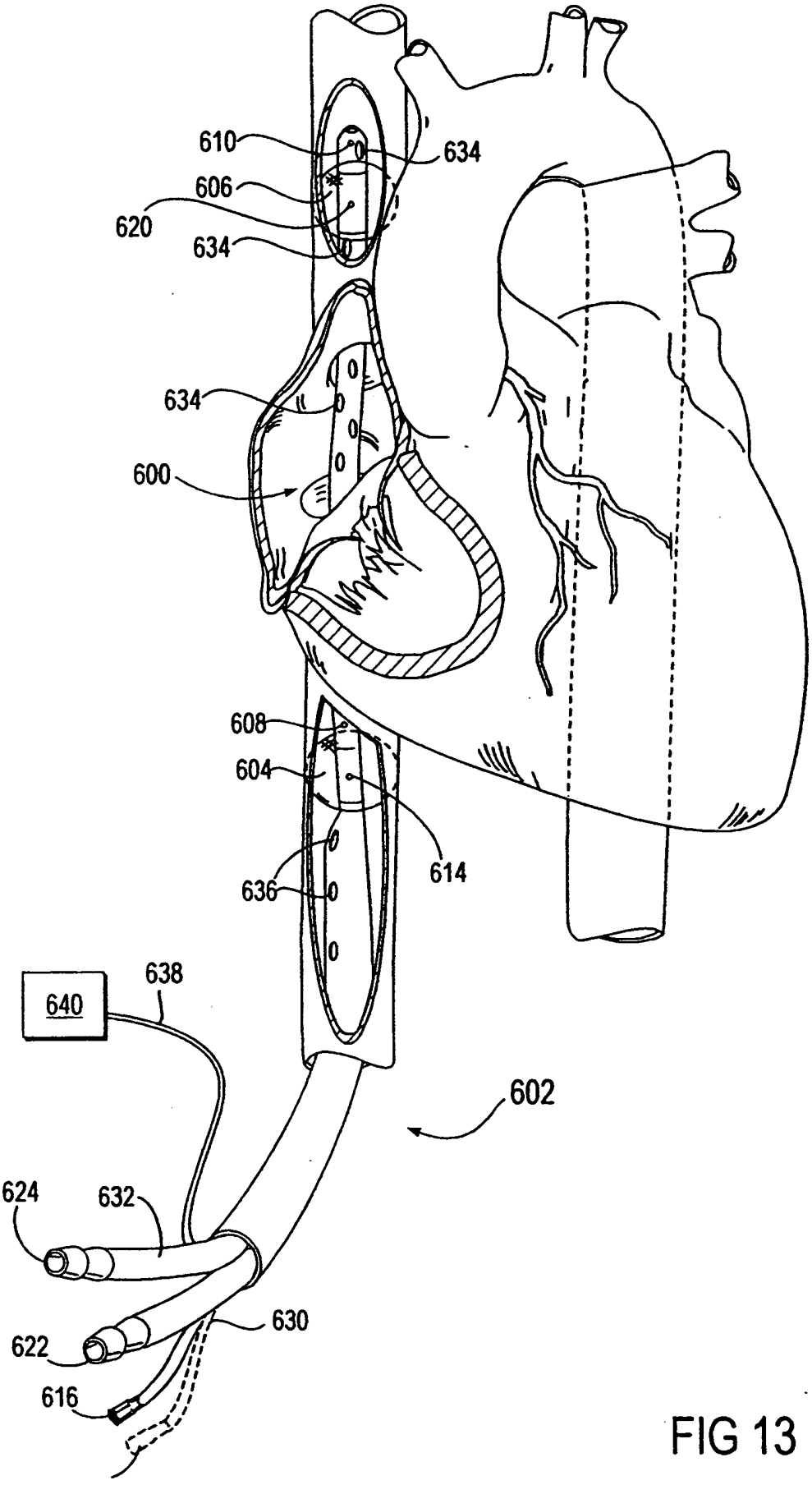
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FIG 13

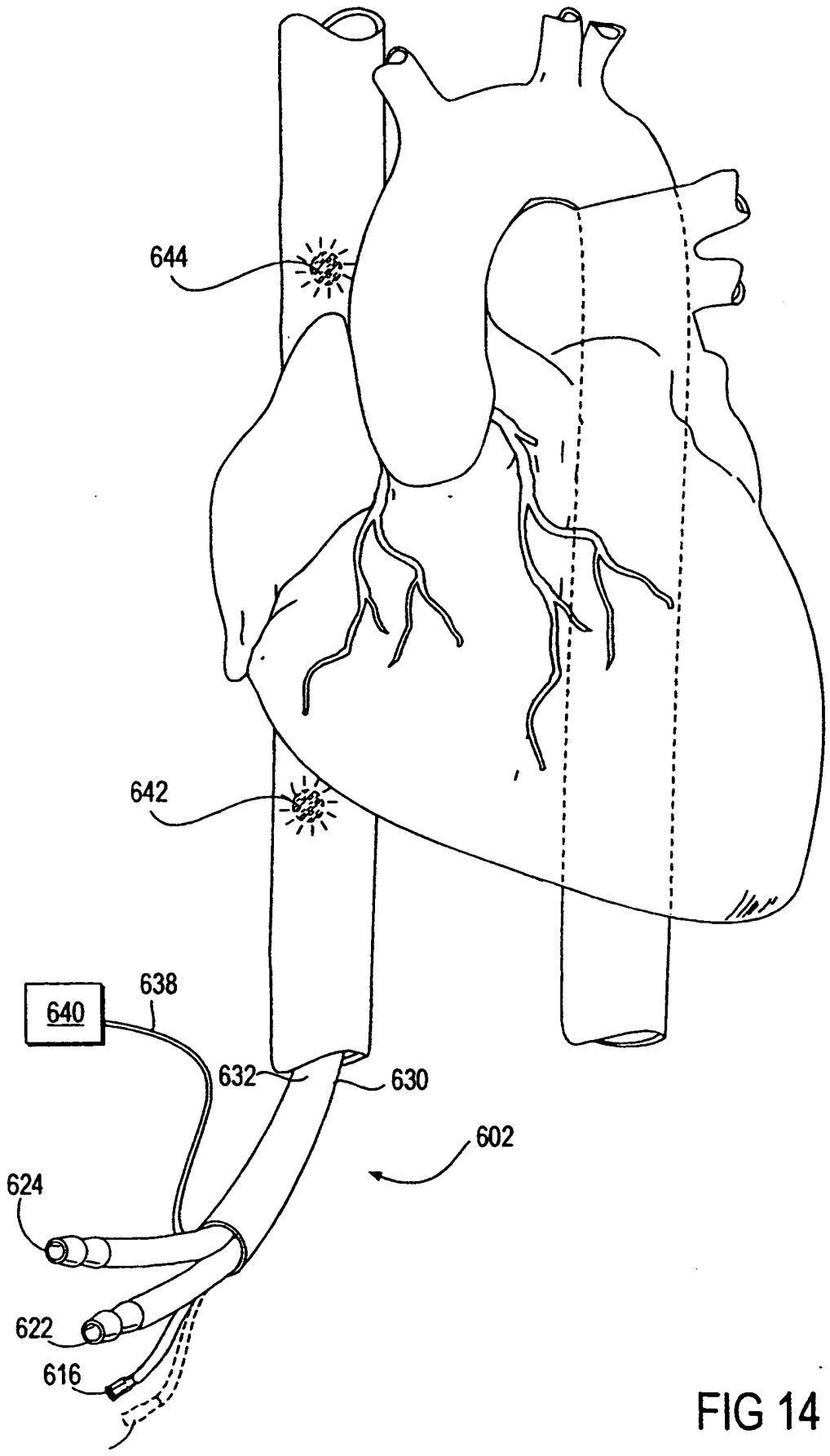


FIG 14

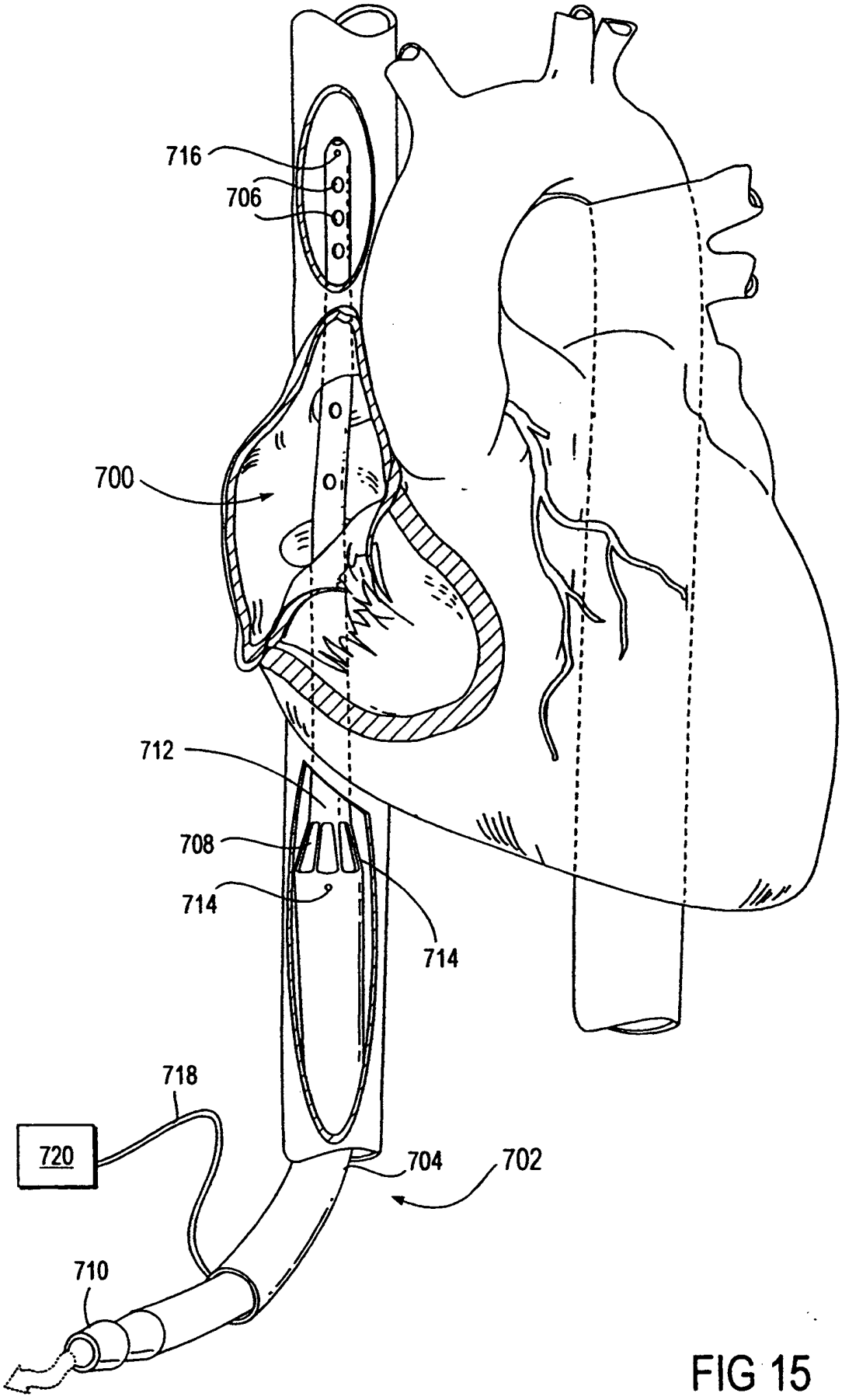


FIG 15

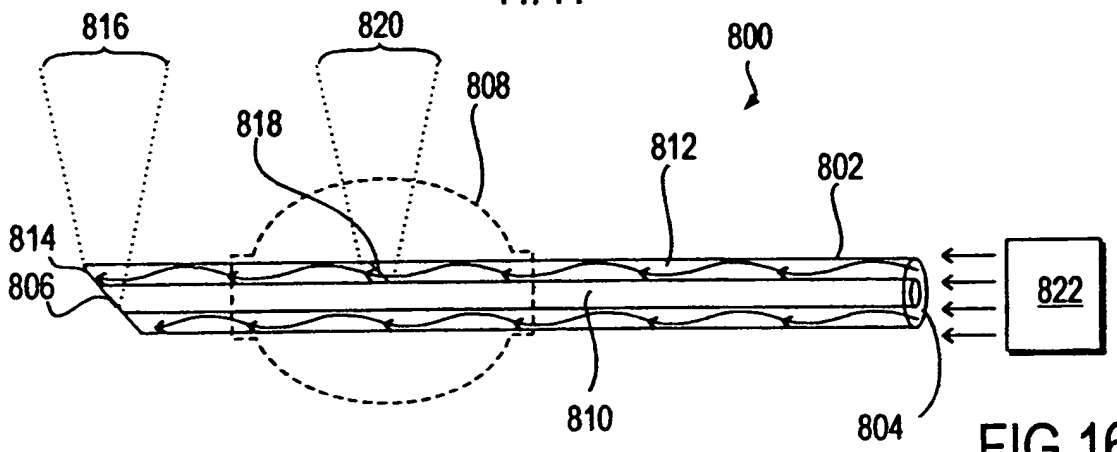


FIG 16

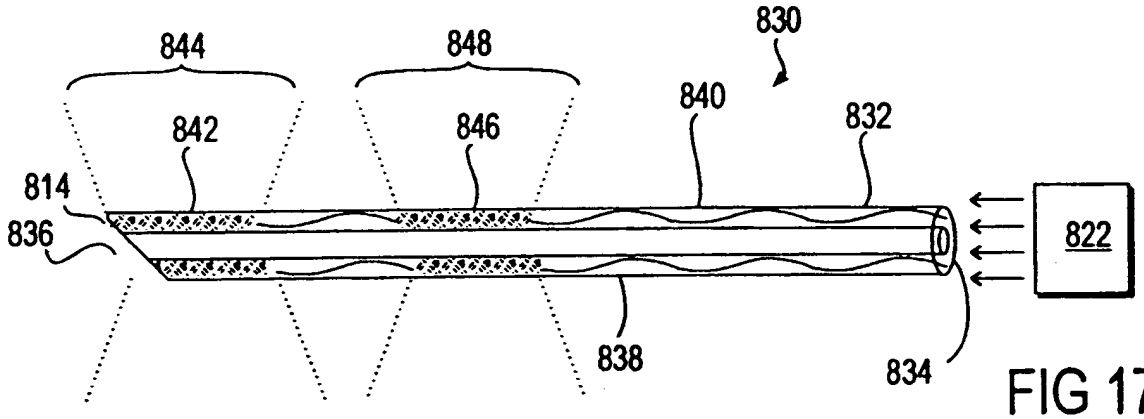


FIG 17

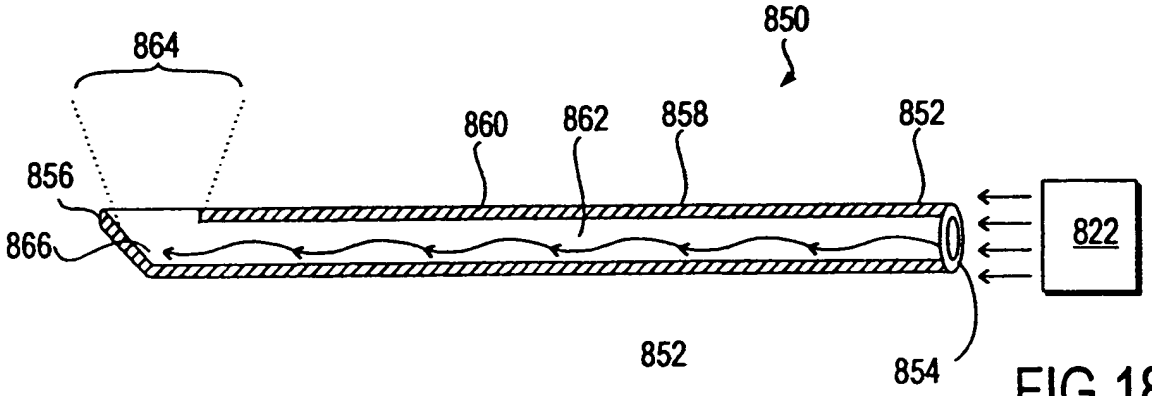


FIG 18

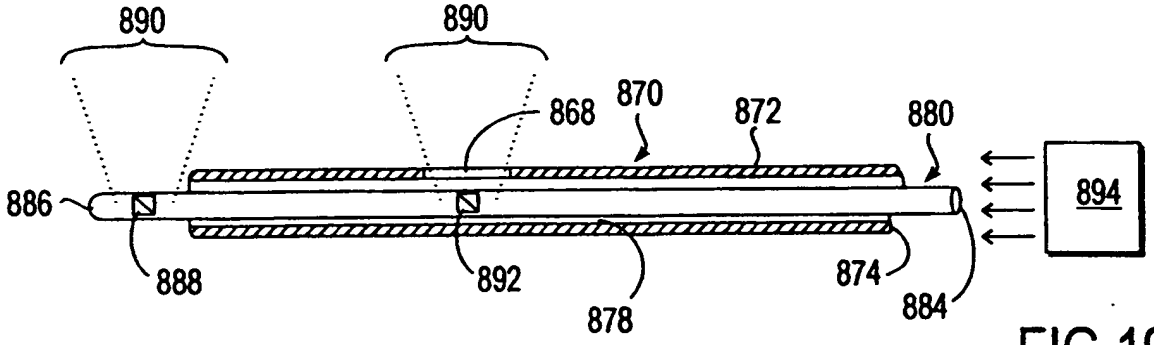


FIG 19

# INTERNATIONAL SEARCH REPORT

Int. ional Application No
PCT/US 99/12870

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M25/01 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | WO 96 40347 A (HEARTPORT INC)<br>19 December 1996 (1996-12-19) | 1-10,15,<br>17,20,<br>23-25,<br>27,50,<br>55-61,<br>63,<br>71-73,<br>76-78 |
| A | page 65, line 17 -page 67, line 14;<br>figures | 29,35,<br>39,40,<br>44,45,48 |

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 20 October 1999 | 26/10/1999 |

| Name and mailing address of the ISA | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL – 2280 HV Rijswijk<br>Tel. (+31–70) 340–2040, Tx. 31 651 epo nl,<br>Fax: (+31–70) 340–3016 | Kousouretas, I |

# INTERNATIONAL SEARCH REPORT

Intr ional Application No
PCT/US 99/12870

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication,where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | US 5 370 640 A (KOLFF JACK)<br>6 December 1994 (1994-12-06)<br>cited in the application | 1-11,13,<br>15,20,<br>22-24,<br>26,28,<br>29,31,<br>33,35,<br>39,40,<br>45-47,<br>49,71,<br>72,74-78 |
| A | the whole document | 50,<br>55-60,62 |
| X | US 5 700 243 A (NARCISO JR HUGH L)<br>23 December 1997 (1997-12-23) | 1-11,13,<br>15,16,<br>20,22-24 |
| A | claim 1; figures | 29,31,<br>33,35,<br>36,40,<br>45-48,<br>71,72,<br>74-78 |
| X | WO 97 37581 A (BERTOLERO RAYMOND S<br>;ENDOSCOPIC TECHNOLOGIES INC (US);<br>BERTOLERO A) 16 October 1997 (1997-10-16)<br>page 21, line 26 -page 24, line 16;<br>figures | 50,52,<br>53,55-59 |
| A | US 5 722 426 A (KOLFF)<br>3 March 1998 (1998-03-03)<br>claims; figures | 1-13,<br>29-31,<br>33,50,71 |
| A | US 4 566 438 A (LIESE GROVER J ET AL)<br>28 January 1986 (1986-01-28)<br>cited in the application<br>abstract; figures | 50,51 |

# INTERNATIONAL SEARCH REPORT

national application No.
PCT/US 99/ 12870

**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 64-70
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT-Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

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PCT/US 99/12870

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